



Estudos clínicos

Bases de investigação clínica para médicos

Firmino Machado, *MD, MSc Statistics, PhDc*

e: firmينو.firminomachado@gmail.com; t: 910961236

f: www.facebook.com/speedstatistics

w: www.speedstatistics.com

0

... da ideia à pergunta...

P

População/ Problem [main]

I

Intervenção/ O que fazemos ao utente sobre o problema: tratamento, rastreio, meio de diagnóstico , exposição

C

Comparador / pode ser uma não intervenção

O

Outcome

T

Tempo

P População

I Intervenção

C Comparador

O Outcome

T Tempo

Em pacientes com furunculose recorrente, realizar antibioterapia comparado com não fazer tratamento, reduz a proporção de recorrência?

Sulodexide for the Prevention of Recurrent Venous Thromboembolism

The Sulodexide in Secondary Prevention of Recurrent Deep Vein Thrombosis (SURVET) Study: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial

Methods and Results—In this multicenter, double-blind study, 615 patients with first-ever unprovoked venous thromboembolism who had completed 3 to 12 months of oral anticoagulant treatment were randomly assigned to sulodexide 500 lipasemic units twice daily or placebo for 2 years, in addition to elastic stockings. The primary efficacy outcome was recurrence of venous thromboembolism. Major or clinically relevant bleeding was the primary safety

PICOT [2]

Randomised clinical trial: mucosal protection combined with acid suppression in the treatment of non-erosive reflux disease – efficacy of Esoxx, a hyaluronic acid–chondroitin sulphate based bioadhesive formulation

Aim

To evaluate whether combined therapy (mucosal protection plus acid suppression) would improve symptom relief compared to PPI treatment alone.

Methods

In a multicenter, randomised, double-blind trial, 154 patients with NERD were randomised to receive Esoxx a hyaluronic acid-chondroitin sulphate based bioadhesive formulation, or placebo, in addition to acid suppression with standard dose PPIs for 2 weeks. Symptoms (heartburn, acid regurgitation, retrosternal pain and acid taste in the mouth) and health-related quality of life (HRQL) were evaluated before and after treatment. The primary endpoint was the proportion of patients with at least a 3-point reduction in the total symptom score.

Non-erosive
reflux disease

1

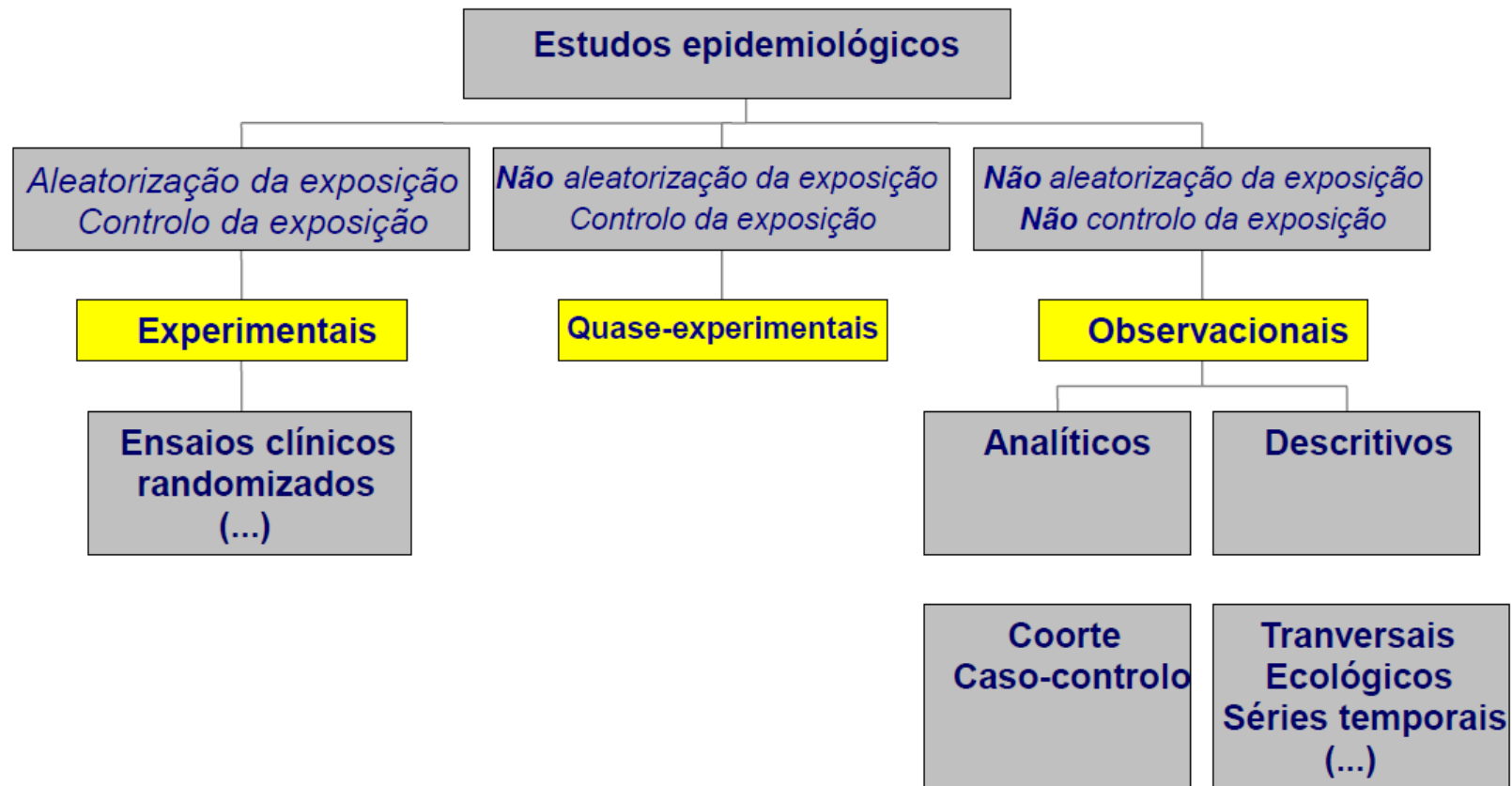
DESENHO DE ESTUDO

(BACKBONE)

Exposição



Outcome



✓

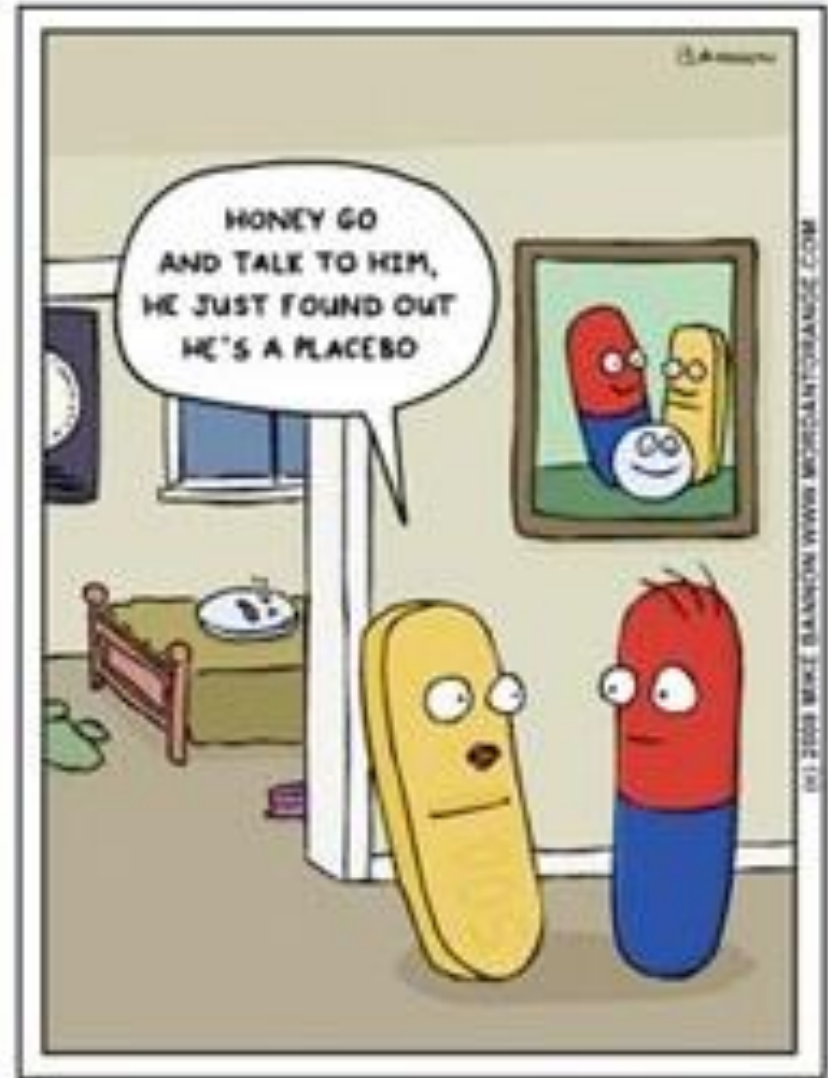
Box 1. Hierarchy of Study Designs for Intended Effects of Therapy

1. Randomised controlled trials
2. Prospective follow-up studies
3. Retrospective follow-up studies
4. Case-control studies
5. Anecdotal: case report and series

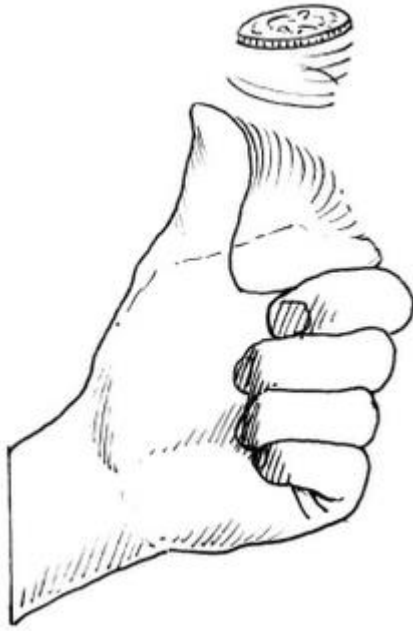
Box 2. Hierarchy of Study Designs for Discovery and Explanation

1. Anecdotal: case reports and series, findings in data, literature
2. Case-control studies
3. Retrospective follow-up studies
4. Prospective follow-up studies
5. Randomised controlled trials

Ensaaios Clínicos







Aim

To evaluate whether combined therapy (mucosal protection plus acid suppression) would improve symptom relief compared to PPI treatment alone.

Intervenção (i) 

Controlo (c) 

$\text{Efeito}(i) = \text{História Natural } (i) + \text{Subjetividade do doente } (i) + \text{Subjetividade do médico } (i) + \text{Efeito da intervenção } (i)$

$\text{Efeito}(c) = \text{História Natural } (i) + \text{Subjetividade do doente } (c) + \text{Subjetividade do médico } (c) + \text{Efeito da intervenção } (c)$

$\text{Efeito}(\text{global}) = \text{Efeito } (i) - \text{Efeito } (c)$

$\text{Efeito}(\text{global}) = \text{Efeito da intervenção } (i) - \text{Efeito da intervenção}(c)$

Intervenção (i) →

Controlo (c) →

Aleatorização

Dupla ocultação

Efeito(i) = ~~História Natural (i)~~ + Subjetividade do doente (i) + Subjetividade do médico (i) + Efeito da intervenção (i)

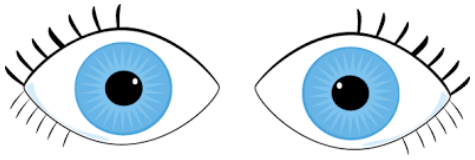
Efeito(c) = ~~História Natural (i)~~ + Subjetividade do doente (i) + Subjetividade do médico (i) + Efeito da intervenção (c)

Efeito(global) = Efeito (i) – Efeito (c)

Efeito(global) = Efeito da intervenção (i) – Efeito da intervenção(c)

blinding refers to keeping trial **participants**, **investigators** (usually health-care providers), or **assessors** (those collecting outcome data) unaware of an **assigned intervention**





Non Blinded / Open Label



OU



OU



+



+



+



+



+



| | % (No./Total) | |
|---|---------------|----------------------|
| | Physicians | Textbook Definitions |
| Interpretations and Definitions | | |
| Single blinding | | |
| Participants | 75 (68/91) | 74 (17/23) |
| Participants and health care providers | 9 (8/91) | 0 |
| Health care providers | 4 (4/91) | 9 (2/23) |
| Investigators* | NA† | 9 (2/23) |
| Judicial assessors‡ | 3 (3/91) | 4 (1/23) |
| Data collectors | 2 (2/91) | 4 (1/23) |
| Other groups | 7 (6/91) | 0 |
| Double blinding | | |
| Participants and health care providers | 38 (35/91) | 43 (12/28) |
| Participants and investigators* | NA† | 21 (6/28) |
| Participants and judicial assessors‡ | 5 (5/91) | 14 (4/28) |
| Participants, health care providers, data collectors, and judicial assessors‡ | 13 (12/91) | 0 |
| Participants, health care providers, data collectors, judicial assessors,‡ and data analysts | 10 (9/91) | 0 |
| Participants, health care providers, and data collectors | 7 (6/91) | 0 |
| Participants, health care providers, data collectors, and data analysts | 7 (6/91) | 0 |
| Participants and data collectors | 5 (5/91) | 4 (1/28) |
| Judicial assessors‡ and assignment to treatment or control | NA† | 4 (1/28) |
| Participants, health care providers, and judicial assessors‡ | 1 (1/91) | 4 (1/28) |
| Participants, health care providers, investigators,* and health care personnel§ | NA† | 4 (1/28) |
| Other groups | 13 (12/91) | 7 (2/28) |
| Triple blinding | | |
| Participants, health care providers, data collectors, judicial assessors,‡ and data analysts | 18 (15/83) | 0 |
| Participants, health care providers, data collectors, judicial assessors,‡ data analysts, and authors | 18 (15/83) | 0 |
| Participants, health care providers, and data collectors | 16 (13/83) | 0 |
| Participants, health care providers, and data analysts | 10 (8/83) | 14 (1/7) |

Physician Interpretations and Textbook Definitions of Blinding Terminology in Randomized Controlled Trials, P. J. Devereaux, P.J. et al., Jama, 2001

Sulodexide for the Prevention of Recurrent Venous Thromboembolism

The Sulodexide in Secondary Prevention of Recurrent Deep Vein Thrombosis (SURVET) Study: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial

Study Design and Intervention

SURVET was a multicenter, multinational, randomized, double-blind, parallel-group, placebo-controlled clinical trial.

Patients, recruiting physicians, physicians or pharmacists delivering the treatments units, physicians or technicians assessing the outcome, and Steering Committee members were blinded to the intervention and to the block size until the end of the statistical analysis.

**Allocation concealment in randomised trials: defending against deciphering**

Allocation concealment refers to the technique used to implement the sequence,⁴ not to generate it.

Generate sequence

Tratamento

A
B
B
A
B
A

Implementação →

Implement sequence

Id Tratamento

1 A
2 B
3 B
4 A
5 B
6 A

TABELA 1

Indecifrabilidade da sequencia

sealed envelope™

★ THE ORIGINAL INTERNET AND TELEPHONE RANDOMISATION SINCE 2001



RANDOMISATION AND ONLINE DATABASES FOR CLINICAL TRIALS

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>



I – Fixed allocation

a) **simples**

b) blocks

c) stratified

II – Adaptativa

Pitfall?

ABABABABABABABABA

A)Simples

B)Blocos

C)Estratificada

ABAB | ABBA | AABB | BBAA

ABAB | ABBBA | ABABBAB |

a) Imbalance

b) Modificação caract. ao longo do tempo

**Sulodexide for the Prevention of Recurrent Venous
Thromboembolism**

**The Sulodexide in Secondary Prevention of Recurrent Deep Vein
Thrombosis (SURVET) Study: A Multicenter, Randomized, Double-Blind,
Placebo-Controlled Trial**

Study Design and Intervention

SURVET was a multicenter, multinational, randomized, double-blind, parallel-group, placebo-controlled clinical trial. Eligible patients were allocated to treatment for 2 years with oral sulodexide (2×250–lipasemic unit capsules twice daily) or matching placebo in a 1:1 ratio based on a computer-generated randomization list in blocks of 4 produced by an independent operating unit.

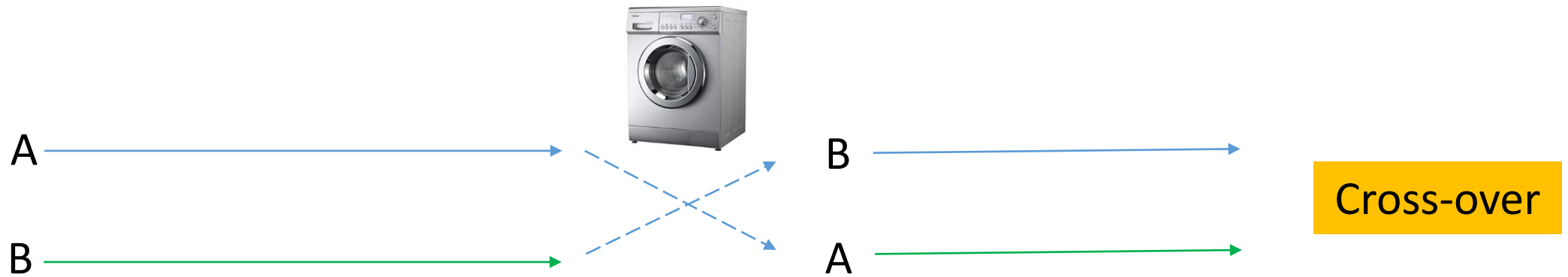
One year intermittent rifaximin plus fibre supplementation vs. fibre supplementation alone to prevent diverticulitis recurrence: A proof-of-concept study

Table 1

Demographic profile of patients and clinical characteristics of diverticulitis history.

| Variable | Controls | Treated | <i>P</i> |
|--|-----------------|-----------------|--------------------|
| Sex | | | |
| Men; <i>N</i> (%) | 55 (62.5%) | 51 (66.2%) | 0.618 ^a |
| Women; <i>N</i> (%) | 33 (37.5%) | 26 (33.8%) | |
| Age | | | |
| Mean \pm SD | 54.7 \pm 13.2 | 53.6 \pm 12.0 | 0.584 ^b |
| <45; <i>N</i> (%) | 22 (25.0%) | 19 (24.7%) | 0.281 ^a |
| 45–54; <i>N</i> (%) | 20 (22.7%) | 26 (33.8%) | |
| 55–64; <i>N</i> (%) | 27 (30.7%) | 15 (19.5%) | |
| 65+; <i>N</i> (%) | 19 (21.6%) | 17 (22.1%) | |
| Time since diagnosis (days) | | | |
| Median [Tukey's hinges] | 54 [41–67] | 53.5 [46–74] | 0.316 ^c |
| <365 days, <i>N</i> (%) | 82 (93.2%) | 67 (87.0%) | 0.182 ^a |
| 365+ days, <i>N</i> (%) | 6 (6.8%) | 10 (13.0%) | |
| Disease localization | | | |
| Sigmoidal, <i>N</i> (%) | 74 (84.1%) | 66 (85.7%) | 0.867 ^a |
| Extrasigmoidal, <i>N</i> (%) | 2 (2.3%) | 2 (2.6%) | |
| Sigmoidal and extrasigmoidal, <i>N</i> (%) | 6 (6.8%) | 6 (7.8%) | |
| Whole colon, <i>N</i> (%) | 6 (6.8%) | 3 (3.9%) | |

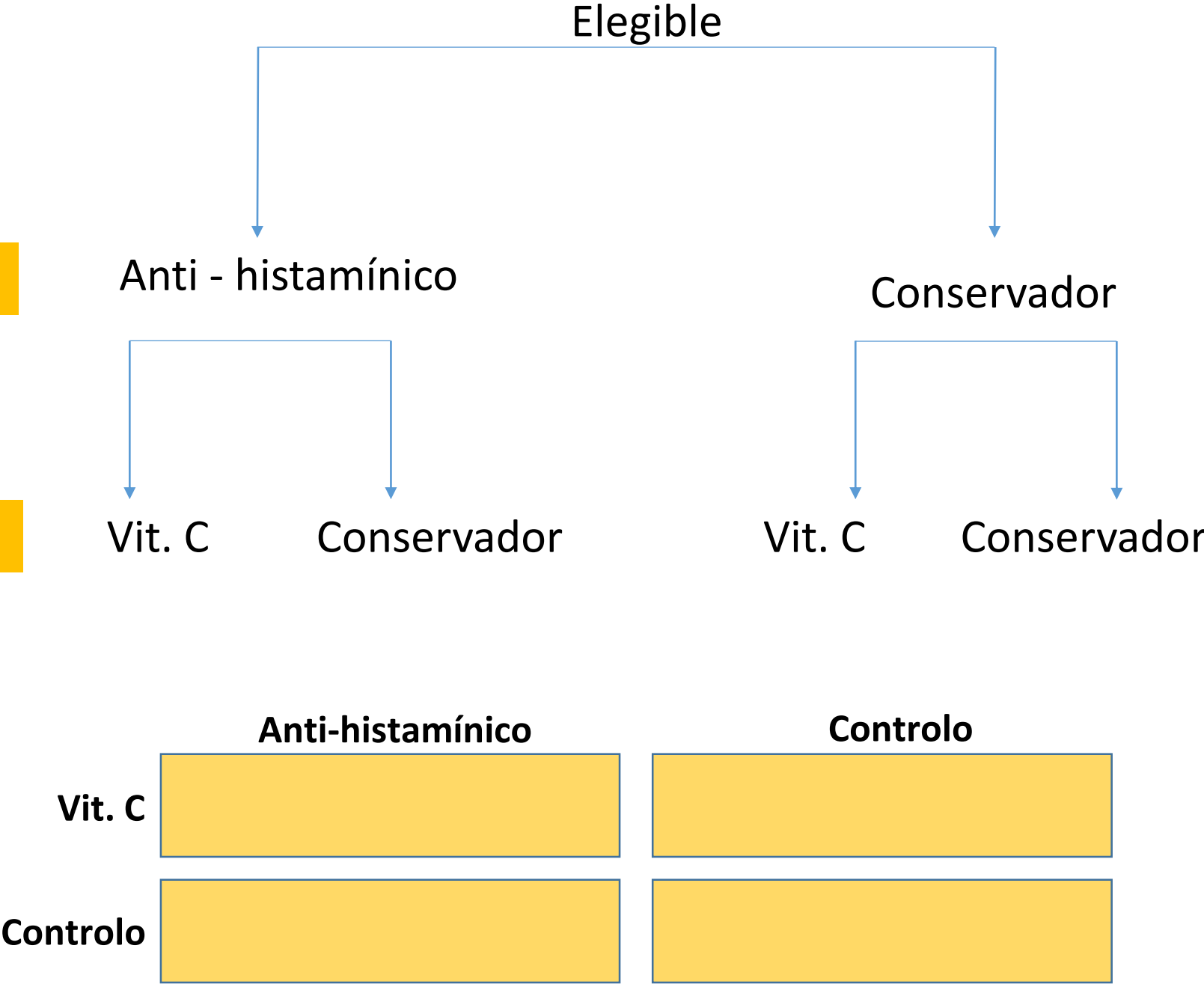
Design



Factorial

Factor 1

Factor 2



Randomised clinical trial: mucosal protection combined with acid suppression in the treatment of non-erosive reflux disease – efficacy of Esoxx, a hyaluronic acid–chondroitin sulphate based bioadhesive formulation

Aim

To evaluate whether combined therapy (mucosal protection plus acid suppression) would improve symptom relief compared to PPI treatment alone.

Study design

The study was multicenter, randomised, double-blind, placebo-controlled with parallel groups.

Randomised clinical trial: mucosal protection combined with acid suppression in the treatment of non-erosive reflux disease
– efficacy of Esoxx, a hyaluronic acid–chondroitin sulphate based bioadhesive formulation

At visit 2, patients were randomised – according to a computer-generated sequence – to receive one standard dose of a PPI (30 min before breakfast) + 10 mL (1 stick) of Esoxx One (single dose stick formulation) or placebo (with the same taste and viscosity, packed in identical, sequentially numbered, containers).

Statistical analysis

The primary endpoint was the treatment efficacy analysis, which was calculated as the proportion of patients with at least 3-point reduction of the total symptom score (TSS).

There were four different secondary endpoints: (i) number of patients with 50% reduction of TSS at final visit, (ii) number of patients with TSS reduction at the final visit, (iii) change TSS after treatment and (iv) HRQL physical and mental items according to the SF-36 questionnaire, which were calculated via a web-based program⁴⁷ and presented as radar plots or spidergrams.⁴⁸

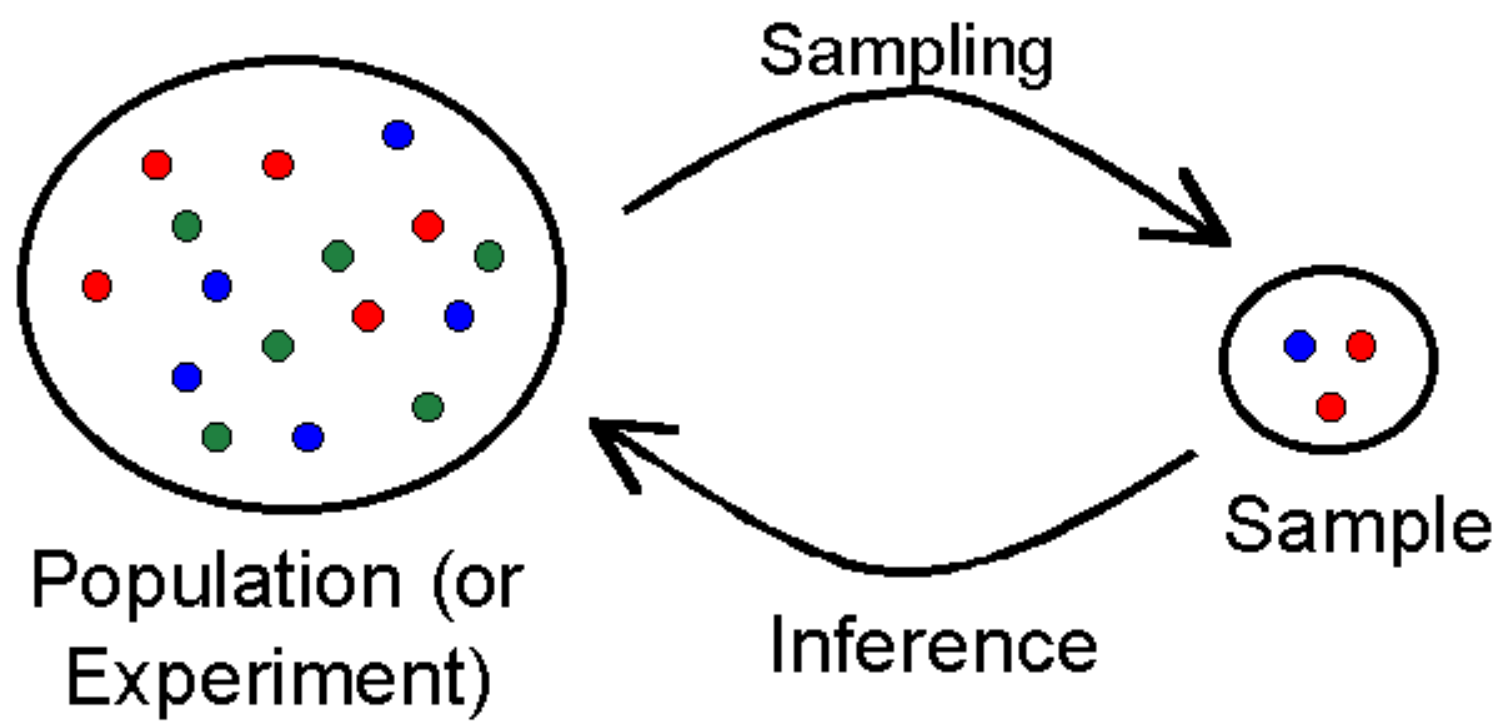
One year intermittent rifaximin plus fibre supplementation vs. fibre supplementation alone to prevent diverticulitis recurrence: A proof-of-concept study

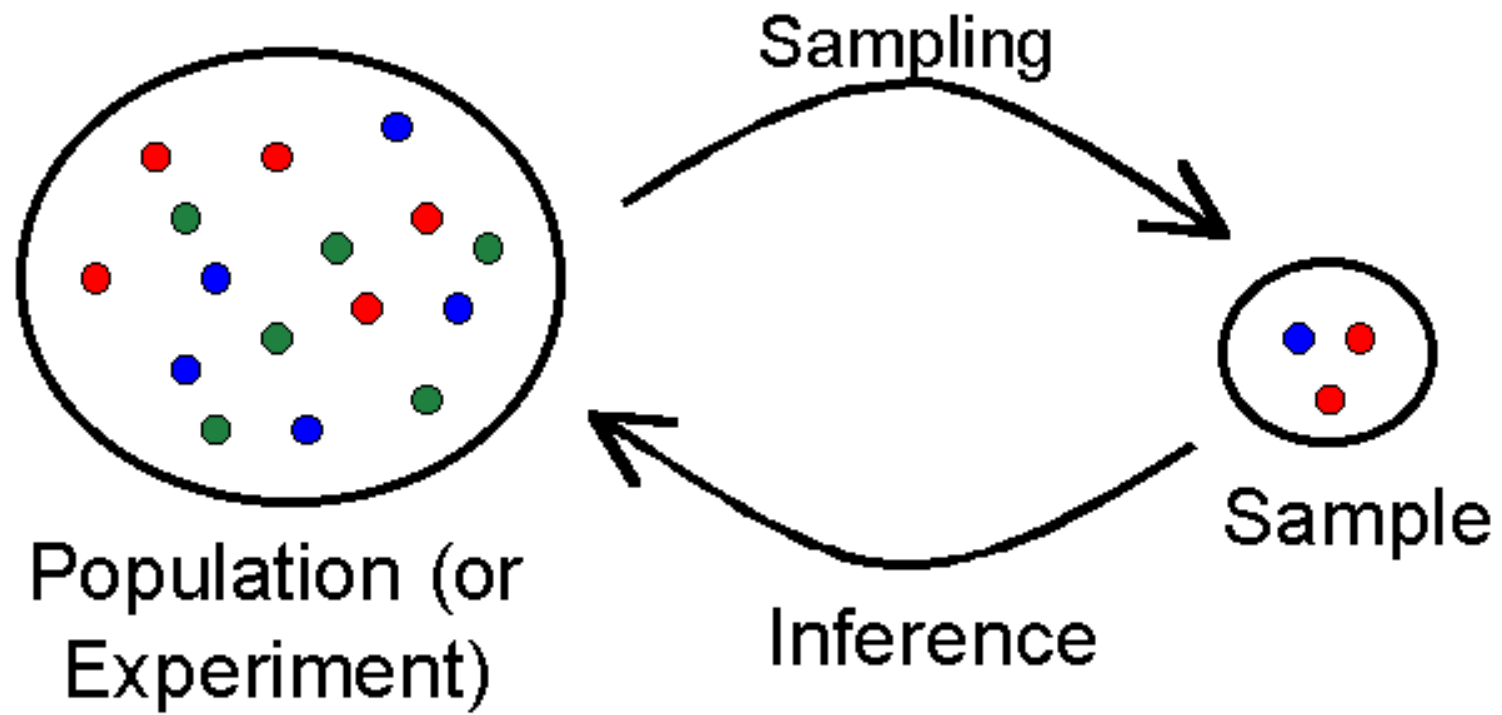
2. Methodology

The study was designed as a randomized open trial in equally sized parallel groups with prospective 1-year follow-up. In order

2

AMOSTRAGEM





a) Representatividade

b) Poder

2.1

DIMENSÃO AMOSTRAL

Eligible for breast cancer screening

Breast Cancer Trial

RANDOMIZATION

Automatic
phone call

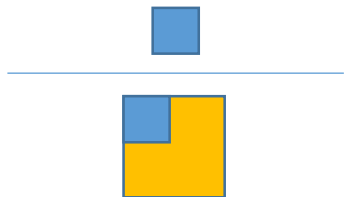
Control

10%

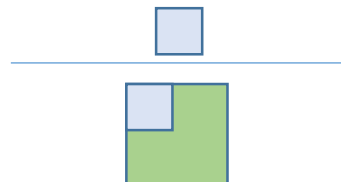
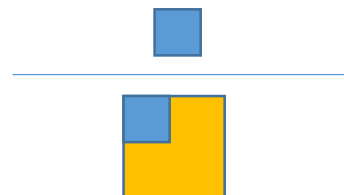
5%

- ✓ **Desenho de estudo**
- ✓ **PICO**
- ✓ **Ética**
- ✓ **Amostragem**

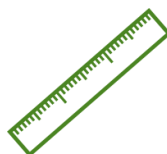
1 proporção
(det. prevalência)



Comparar 2
proporções



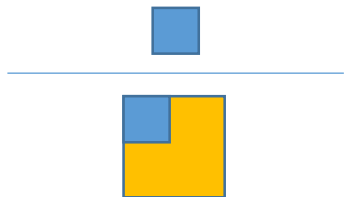
Comparar 2
médias



Caso controlo
OR

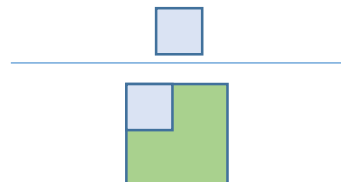
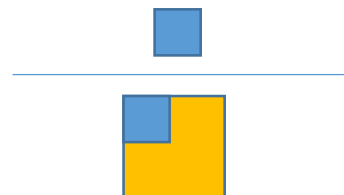
Coorte
RR

1 proporção
(det. prevalência)



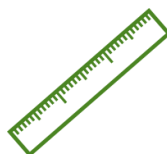
Cross Sectional

Comparar 2
proporções



Experimentais

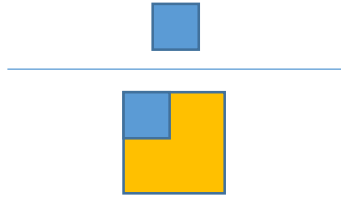
Comparar 2
médias



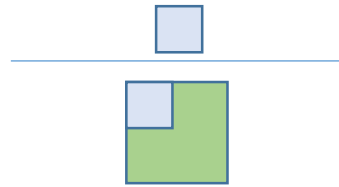
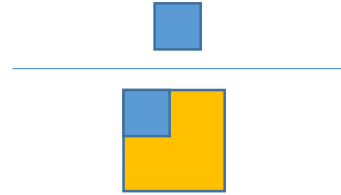
Caso controlo
OR

Coorte
RR

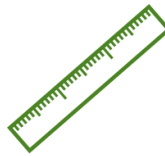
1 proporção
(det. prevalência)



Comparar 2
proporções

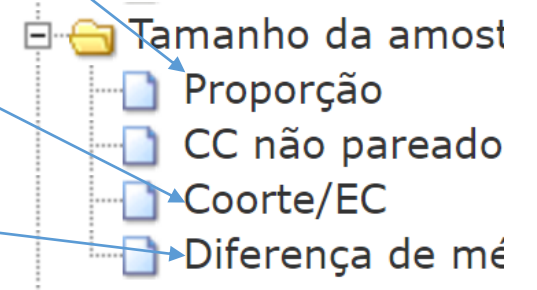


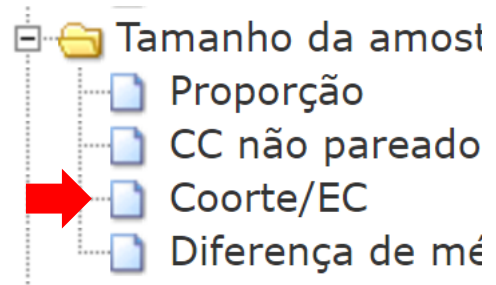
Comparar 2
médias



Caso controlo
OR

Coorte
RR





| Tamanho da Amostra: Transversal, Coorte, & Ensaios Clínicos Aleatórios | | |
|--|----|-------------------------------|
| Nível de confiança bilateral(%) | 95 | (1- α) geralmente 95% |
| Poder (1-beta ou % probabilidade de detecção) | 80 | Geralmente 80% |
| Razão de não expostos para expostos na amostra | 1 | Para amostras iguais, use 1.0 |
| Porcentagem de não expostos positivos | 5 | Entre 0,0 e 99,9 |
| Por favor, informe um dos seguintes. Os outros serão calculados. | | |
| Odds Ratio | | |
| Porcentagem de expostos positivos | | Entre 0,0 e 99,9 |
| Razão Risco/prevalência | | |
| Diferença Risco/prevalência | | Entre -99,99 e 99,99 |

Proporção » Braços do trial

Tamanho da Amostra: Transversal, Coorte, & Ensaios Clínicos Aleatórios

| | | |
|--|-------|-------------------------------|
| Nível de confiança bilateral(%) | 95 | (1-alfa) geralmente 95% |
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| Razão de não expostos para expostos na amostra | 1 | Para amostras iguais, use 1.0 |
| Porcentagem de não expostos positivos | 5 | Entre 0,0 e 99,9 |
| Por favor, informe um dos seguintes. Os outros serão calculados. | | |
| Odds Ratio | 2.11 | |
| Porcentagem de expostos positivos | 10.00 | Entre 0,0 e 99,9 |
| Razão Risco/prevalência | 2 | |
| Diferença Risco/prevalência | 5.00 | Entre -99,99 e 99,99 |

Tamanho da Amostra: Transversal, Coorte, & Ensaios Clínicos Aleatórios

| | |
|--|-----|
| Nível de significância bilateral(1-alpha) | 95 |
| Poder (1-beta,% probabilidade de detecção) | 80 |
| Razão de tamanho da amostra, Expostos/Não Expostos | 1 |
| Porcentagem de Não Expostos positivos | 5 |
| Porcentagem de Expostos positivos | 10 |
| Odds Ratio: | 2.1 |
| Razão de risco/prevalência | 2 |
| Diferença de risco/prevalência | 5 |

| | Kelsey | Fleiss | Fleiss com CC |
|----------------------------------|--------|--------|---------------|
| Tamanho da amostra - Expostos | 437 | 436 | 475 |
| Tamanho da amostra- Não expostos | 437 | 436 | 475 |
| Tamanho total da amostra | 874 | 872 | 950 |

Referências

Kelsey e outros, Métodos em Epidemiologia Observacional 2 Edição, Tabela 12-15

Fleiss, Métodos Estadísticos para Relações e Proporções, fórmulas 3.18&, 3.19

CC= correção de continuidade

Os resultados são arredondados para os inteiros mais próximos.

FAIL REJECT
 H_0

REJECT
 H_0

H_0 TRUE



Tipo I

H_0 FALSE

Tipo II

 $1-\beta$ (Power)

Sulodexide for the Prevention of Recurrent Venous Thromboembolism

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Methods and Results—In this multicenter, double-blind study, XXX patients with first-ever unprovoked venous thromboembolism who had completed 3 to 12 months of oral anticoagulant treatment were randomly assigned to sulodexide 500 lipasemic units twice daily or placebo for 2 years, in addition to elastic stockings. The primary efficacy outcome was recurrence of venous thromboembolism. Major or clinically relevant bleeding was the primary safety

Statistical Analysis

Assuming an incidence of recurrent VTE with standard care of $\approx 17.5\%$ in 2 years^{3–7} and hypothesizing a 50% relative reduction by adding sulodexide,¹⁸ we determined that a total of XXX patients (\approx XXX per group) had 90% power to show superiority of sulodexide over placebo at a 2-sided level of $\alpha=0.05$.

Sulodexide for the Prevention of Recurrent Venous Thromboembolism

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Statistical Analysis

Assuming an incidence of recurrent VTE with standard care of $\approx 17.5\%$ in 2 years^{3–7} and hypothesizing a 50% relative reduction by adding sulodexide,¹⁸ we determined that a total of 620 patients (≈ 310 per group) had 90% power to show superiority of sulodexide over placebo at a 2-sided level of $\alpha=0.05$.

**População
Asiática**

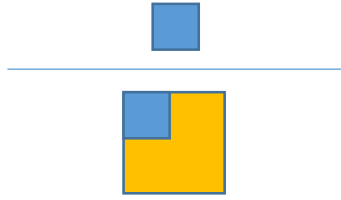
Controlo

Bisoprolol

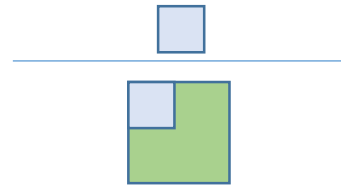
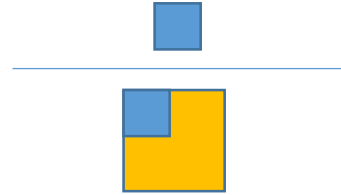
Controlo de pressão
arterial sistólica e
diastólica

- ✓ Desenho de estudo
- ✓ PICO
- ✓ Amostragem
- ✓ Ética

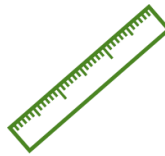
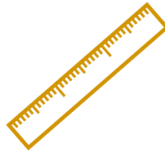
1 proporção
(det. prevalência)



Comparar 2
proporções

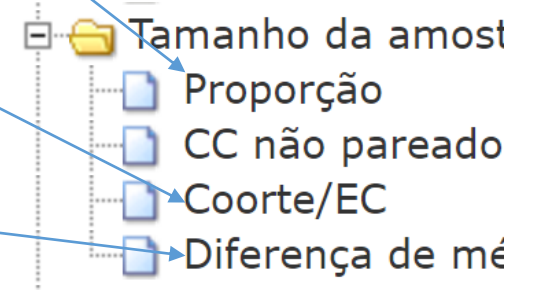


Comparar 2
médias



Caso controlo
OR

Coorte
RR



**The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II):
a randomised trial**

| Characteristics | Placebo (n=1320) | Bisoprolol (n=1327) |
|---|-----------------------------|--------------------------------|
| Demographic | | |
| Mean (range) age (years) | 61 (22–80) | 61 (26–80) |
| Sex (M/F) | 1062 (80%)/ 258 (20%) | 1070 (81%)/ 257 (19%) |
| NYHA class | | |
| III | 1096 (83%) | 1106 (83%) |
| IV | 224 (17%) | 221 (17%) |
| Heart failure | | |
| Documented ischaemic heart disease | 654 (50%) | 662 (50%) |
| Primary dilated cardiomyopathy | 157 (12%) | 160 (12%) |
| Others* | 509 (40%) | 505 (38%) |
| Duration of heart failure (median/mean) | 2·31/3·60 | 2·25/3·49 |
| Mean (SD) systolic blood pressure (mm Hg) | 130·2 (19·5) | 129·2 (19·2) |
| Mean (SD) diastolic blood pressure (mm Hg) | 80·0 (10·9) | 79·4 (11·2) |
| Mean (SD) heart rate (beats/min) | 81·0 (15·5) | 79·9 (14·5) |
| Mean (SD) left-ventricular ejection fraction (%) | 27·6 (5·5) | 27·5 (6·0) |
| Mean (SD) left-ventricular end-diastolic diameter (cm) | 6·7 (0·9) | 6·7(0·9) |

| Tamanho da amostra para comparar duas médias | | | | | |
|---|---------|----|--|---|--|
| Intervalo de confiança % (bilateral) | | 95 | Informe um valor entre 0 e 100, geralmente 95% | | |
| Poder | | 80 | Informe um valor entre 0 e 100, geralmente 80% | | |
| Razão do tamanho da amostra (Grupo 2/Grupo 1) | | 1 | | | |
| | Grupo 1 | | Grupo 2 | Informe as médias OU as diferenças na próxima linha | |
| Média | 130.2 | e | 129.2 | ou Diferença | |
| Desv. Pad. | 19.5 | | 19.2 | Entre o Desv. Padrão OU Variância de cada grupo | |
| Variância | | | | | |

Tamanho da amostra para comparar duas médias

| Dados de entrada | | | |
|--|---------|---------|------------|
| Intervalo de confiança (bilateral) | | 95% | |
| Poder | | 80% | |
| Razão do tamanho da amostra (Grupo2/Grupo 1) | | 1 | |
| | Grupo 1 | Grupo 2 | Diferença* |
| Média | 130.2 | 129.2 | 1 |
| Desvio padrão | 19.5 | 19.2 | |
| Variância | 380.25 | 368.64 | |
| | | | |
| Tamanho da amostra do grupo 1 | | 5878 | |
| Tamanho da amostra do grupo 2 | | 5878 | |
| Tamanho total da amostra | | 11756 | |

*Diferença entre as médias

| Tamanho da amostra para comparar duas médias | | | | | |
|---|---------|----|--|---|--|
| Intervalo de confiança % (bilateral) | | 95 | Informe um valor entre 0 e 100, geralmente 95% | | |
| Poder | | 80 | Informe um valor entre 0 e 100, geralmente 80% | | |
| Razão do tamanho da amostra (Grupo 2/Grupo 1) | | 1 | | | |
| | Grupo 1 | | Grupo 2 | Informe as médias OU as diferenças na próxima linha | |
| Média | 80 | e | 79.4 | ou Diferença | |
| Desv. Pad. | 10.9 | | 11.2 | Entre o Desv. Padrão OU Variância de cada grupo | |
| Variância | | | | | |

Tamanho da amostra para comparar duas médias

| Dados de entrada | | | |
|--|---------|---------|------------|
| Intervalo de confiança (bilateral) | | 95% | |
| Poder | | 80% | |
| Razão do tamanho da amostra (Grupo2/Grupo 1) | | 1 | |
| | Grupo 1 | Grupo 2 | Diferença* |
| Média | 80 | 79.4 | 0.6 |
| Desvio padrão | 10.9 | 11.2 | |
| Variância | 118.81 | 125.44 | |
| | | | |
| Tamanho da amostra do grupo 1 | | 5325 | |
| Tamanho da amostra do grupo 2 | | 5325 | |
| Tamanho total da amostra | | 10650 | |

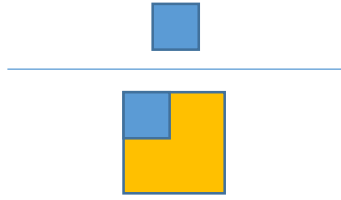
Estudo da Prevalência de DPOC nos utentes do ACeS Feira/Arouca

Pop=342.000
Precisão 1%

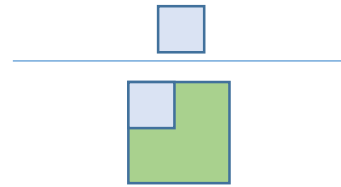
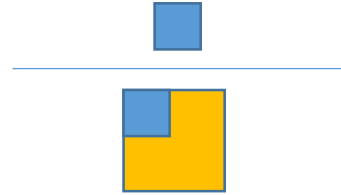


- ✓ Desenho de estudo
- ✓ PICO
- ✓ Amostragem
- ✓ Ética

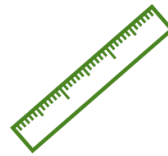
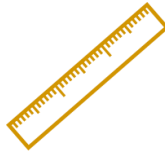
1 proporção
(det. prevalência)



Comparar 2
proporções



Comparar 2
médias



Caso controlo
OR

Coorte
RR

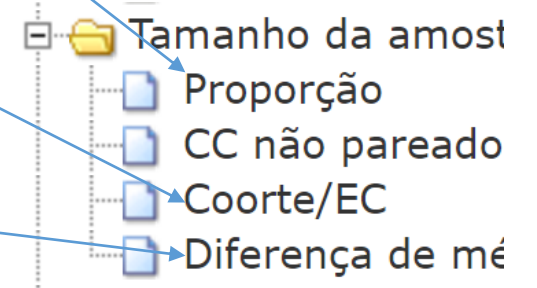
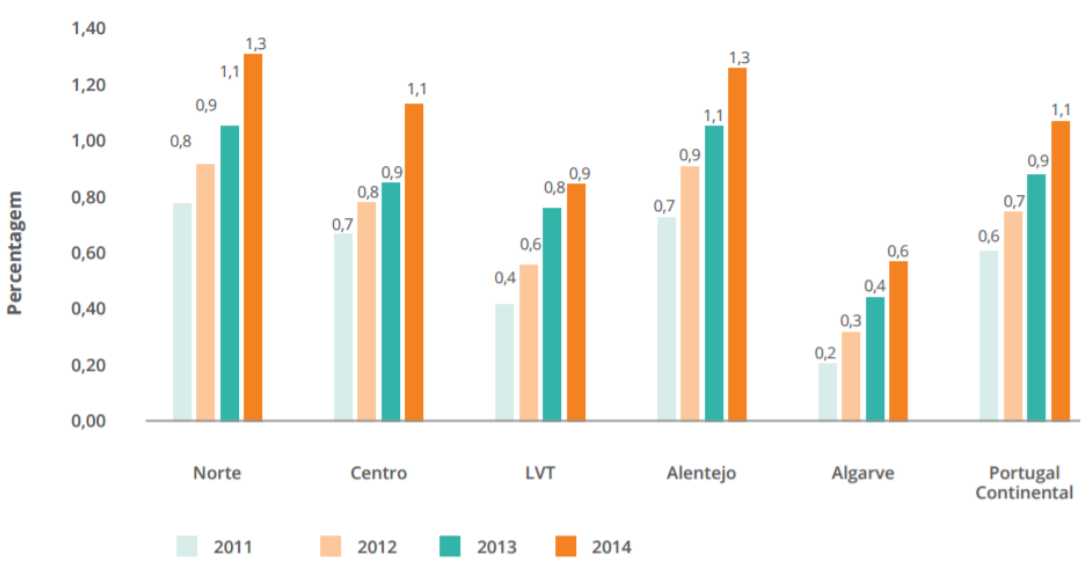


FIGURA 35

PERCENTAGEM DE UTENTES COM DIAGNÓSTICO DE DPOC ENTRE OS UTENTES INSCRITOS ATIVOS EM CUIDADOS DE SAÚDE PRIMÁRIOS, PORTUGAL CONTINENTAL E POR REGIÃO DE SAÚDE (2011 A 2014)





PORTUGAL
Doenças Respiratórias
em Números - 2015

Programa Nacional para
as Doenças Respiratórias



revista portuguesa de

PNEUMOLOGIA

portuguese journal of pulmonology

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ARTIGO ORIGINAL

Doença Pulmonar Obstrutiva Crónica em Portugal: estudo Pneumobil (1995) e estudo de prevalência de 2002 revisitados

Results: The prevalence of COPD was 8.96% in Pneumobil and 5.34% in the 2002 study. In both studies, presence of COPD was greater in males and there was a positive association between presence of COPD and older age groups. Smokers and ex-smokers showed a higher proportion of cases of COPD.

- Tamanho da amostra
- Proporção
- CC não pareado
- Coeficiente/EC
- Diferença de média

| Tamanho amostral para % de frequência em uma população (amostras aleatórias) | | |
|--|---------|--|
| Tamanho da população | 1000000 | Caso seja grande, deixe como um milhão |
| Frequência (p) antecipada % | 50 | Valor entre 0 e 99.99. Se não for conhecido, use 50% |
| Limites de confiança como +/- porcentagem de 100 | 5 | Precisão absoluta % |
| Efeito de desenho (para estudos com amostras complexas—EDFF) | 1.0 | 1.0 para amostras aleatórias |

| Tamanho amostral para % de frequência em uma população (amostras aleatórias) | | |
|--|--------|--|
| Tamanho da população | 342000 | Caso seja grande, deixe como um milhão |
| Frequência (p) antecipada % | 8 | valor entre 0 e 99.99. Se não for conhecido, use 50% |
| Limites de confiança como +/- porcentagem de 100 | 1 | Precisão absoluta % |
| Efeito de desenho (para estudos com amostras complexas—EDFF) | 1 | 1.0 para amostras aleatórias |

IntervaloConfiança (%)
95%

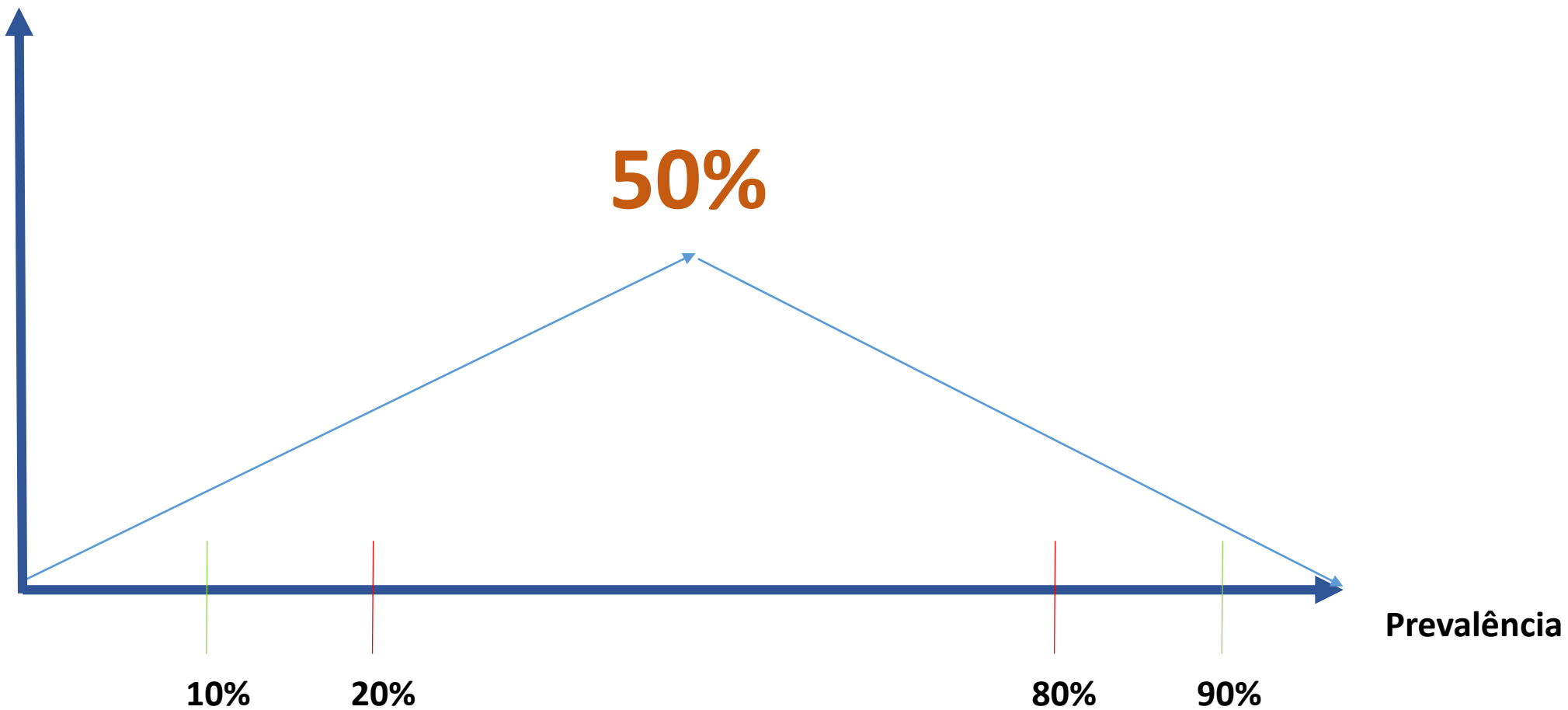
Tamanho da amostra
2805

| Tamanho amostral para % de frequência em uma população (amostras aleatórias) | | |
|--|--------|--|
| Tamanho da população | 342000 | Caso seja grande, deixe como um milhão |
| Frequência (p) antecipada % | 5.34 | valor entre 0 e 99.99. Se não for conhecido, use 50% |
| Limites de confiança como +/- porcentagem de 100 | 1 | Precisão absoluta % |
| Efeito de desenho (para estudos com amostras complexas—EDFF) | 1 | 1.0 para amostras aleatórias |

IntervaloConfiança (%)
95%

Tamanho da amostra
1931

Dim. Amostral



VARIAS CONDIÇÕES

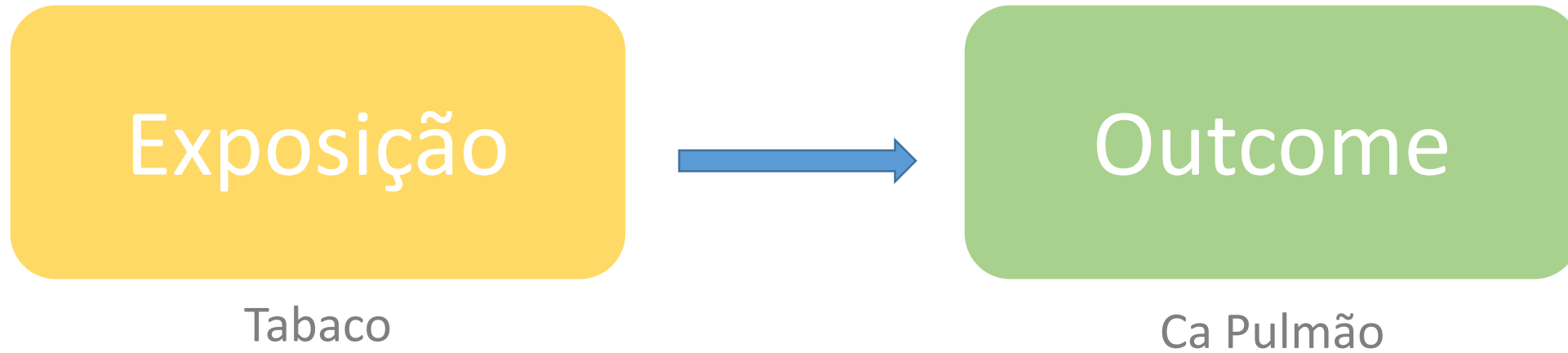
DPOC

HTA

DIABETES

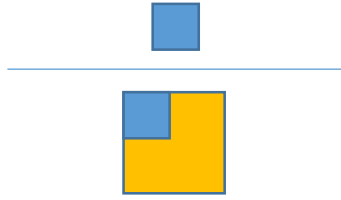
Caso-Controlo

OR=8,3
Controlos expostos ao fumo=3%

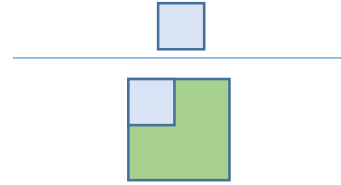
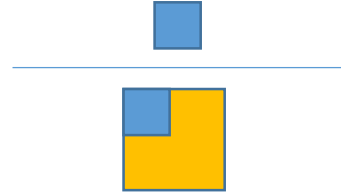


- ✓ Desenho de estudo
- ✓ PICO
- ✓ Amostragem
- ✓ Ética

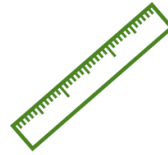
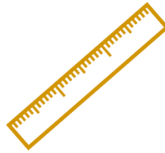
1 proporção
(det. prevalência)



Comparar 2
proporções

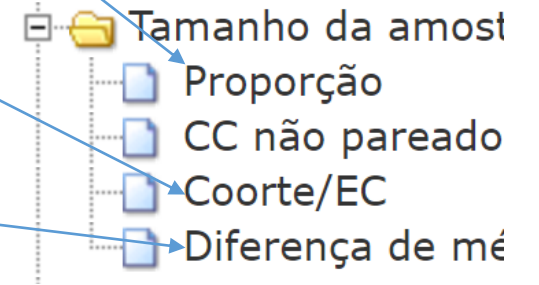


Comparar 2
médias



Caso controlo
OR

Coorte
RR



- Tamanho da amostra
- Proporção
- CC não pareado
- Coorte/EC
- Diferença de média



Tamanho da amostra para estudo de casos- controle não pareados

| | | |
|--|-----|--------------------------------|
| Nível de confiança bilateral | 95 | (1 - α) geralmente 95% |
| Poder (% de probabilidade de detecção) | 80 | Geralmente 80% |
| Razão de controles por caso | 1.0 | Para amostras iguais, use 1.0 |
| Porcentagem de controles expostos | 40 | Entre 0.0 e 99.99 |
| Por favor, informe um dos seguintes. O outro será calculado. | | |
| Odds Ratio | | |
| Porcentagem de casos com exposição | | Entre 0.0 e 99.99 |

| Tamanho da amostra para estudo de casos- controle não pareados | | |
|---|-------|-------------------------------|
| Nível de confiança bilateral | 95 | (1-alfa) geralmente 95% |
| Poder (% de probabilidade de detecção) | 80 | Geralmente 80% |
| Razão de controles por caso | 1.0 | Para amostras iguais, use 1.0 |
| Porcentagem de controles expostos | 3 | Entre 0.0 e 99.99 |
| Por favor, informe um dos seguintes. O outro será calculado. | | |
| Odds Ratio | 8.3 | |
| Porcentagem de casos com exposição | 20.43 | Entre 0.0 e 99.99 |

| | Kelsey | Fleiss | Fleiss com CC |
|--------------------------------|--------|--------|---------------|
| Tamanho da amostra - Casos | 54 | 53 | 64 |
| Tamanho da amostra - Controles | 54 | 53 | 64 |
| Tamanho total da amostra | 108 | 106 | 128 |

2.1.1

DIMENSÃO AMOSTRAL

(aspectos práticos)

**Dividir valor pela %
de resposta/sucesso**

2.2

TÉCNICA DE AMOSTRAGEM

Tipos de amostragem

Amostras **não probabilísticas**

Amostras **probabilísticas**

- Aleatória Simples/Elementar

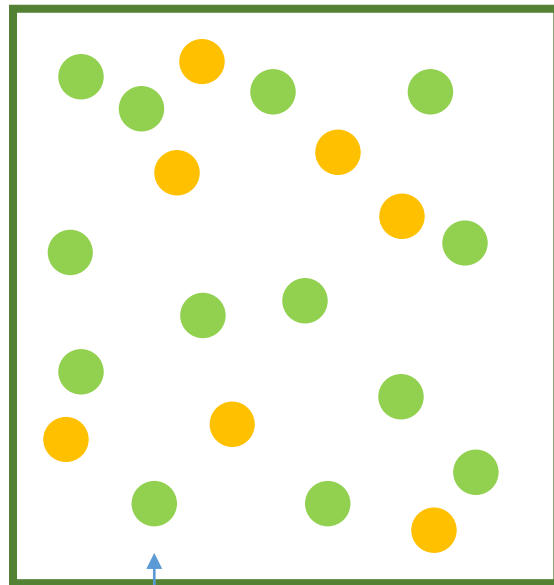
- Estratificada

- Clusters

- Multietápica

Amostragem **probabilística**

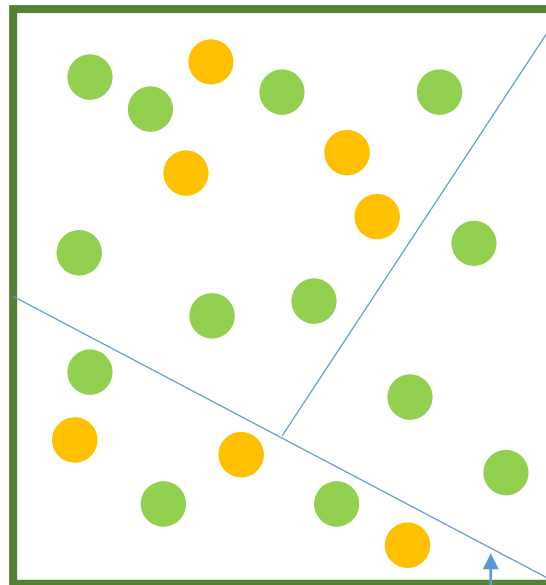
Aleatória Simples



Elemento da
população

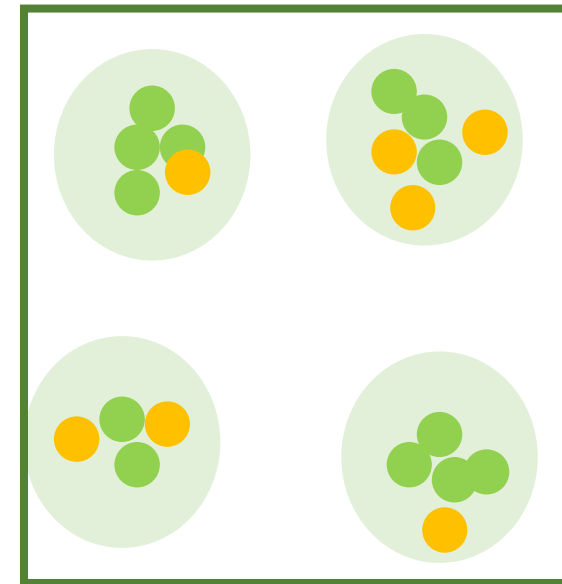
Unidade
amostral

Estratificada



Estrato

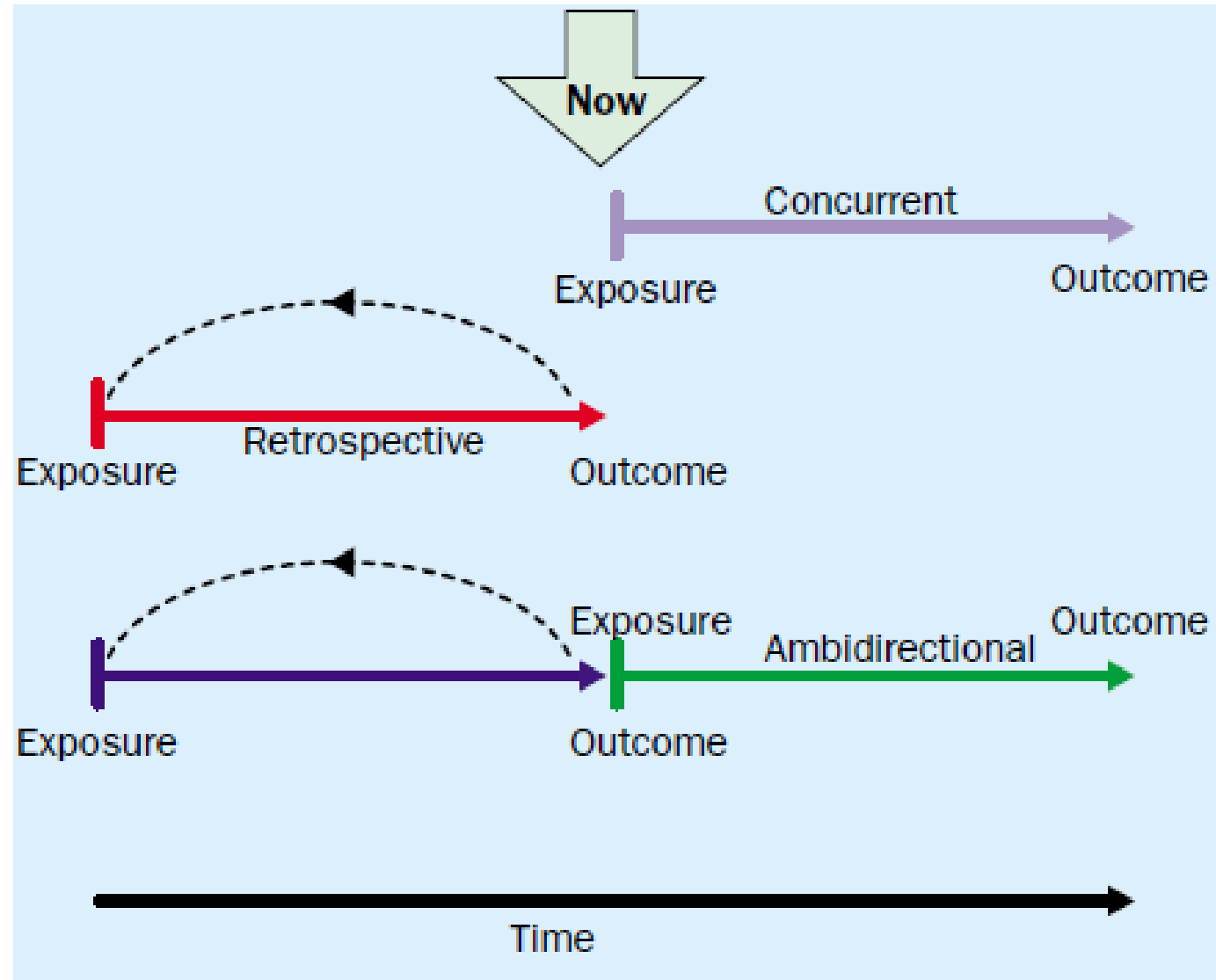
Cluster



Determinação
objetiva
Ø Recall



Survey
previamente
realizado

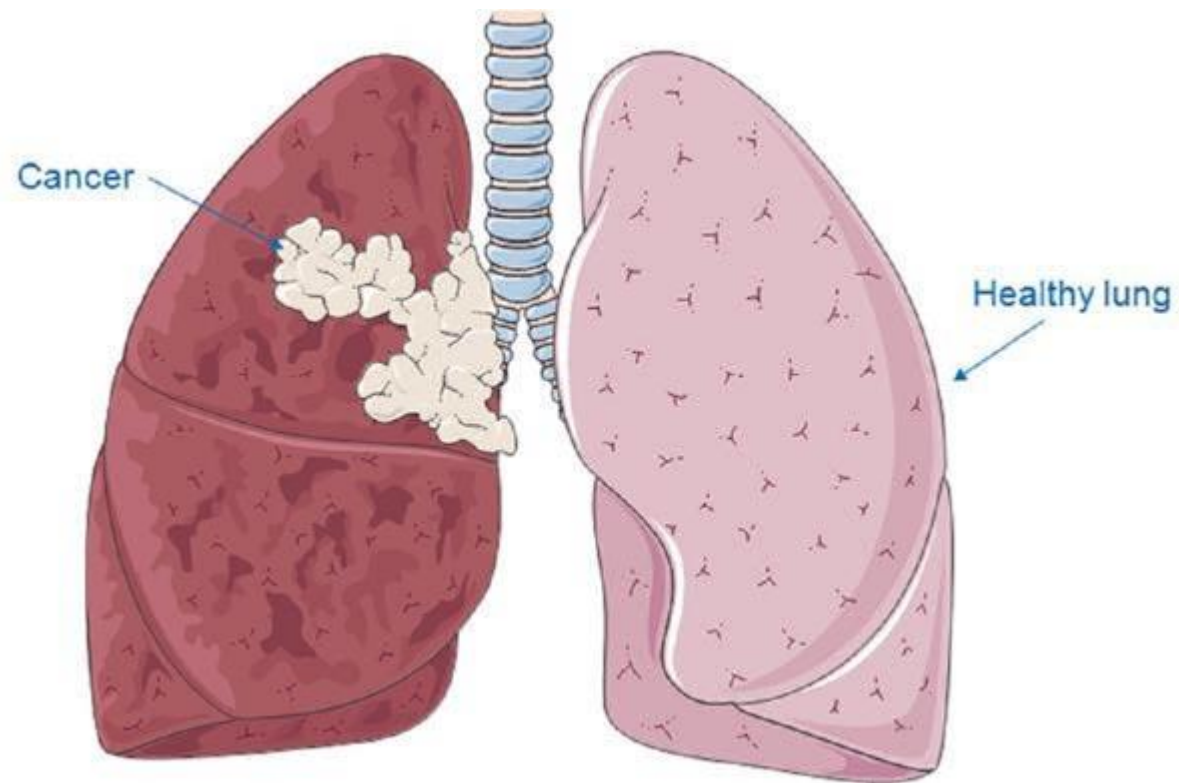


Retrospectivo

O outcome ocorre antes do início do estudo

Prospetivo

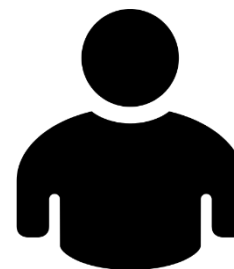
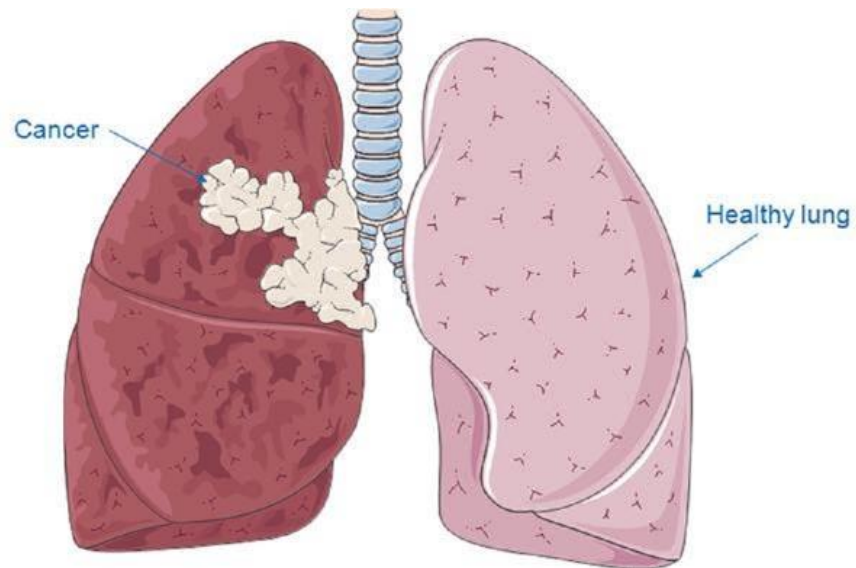
O outcome ocorre após o início do estudo



- 1) Casos Vs. Controlos
- 2) Operacionalização
- 3) Obtenção de informação

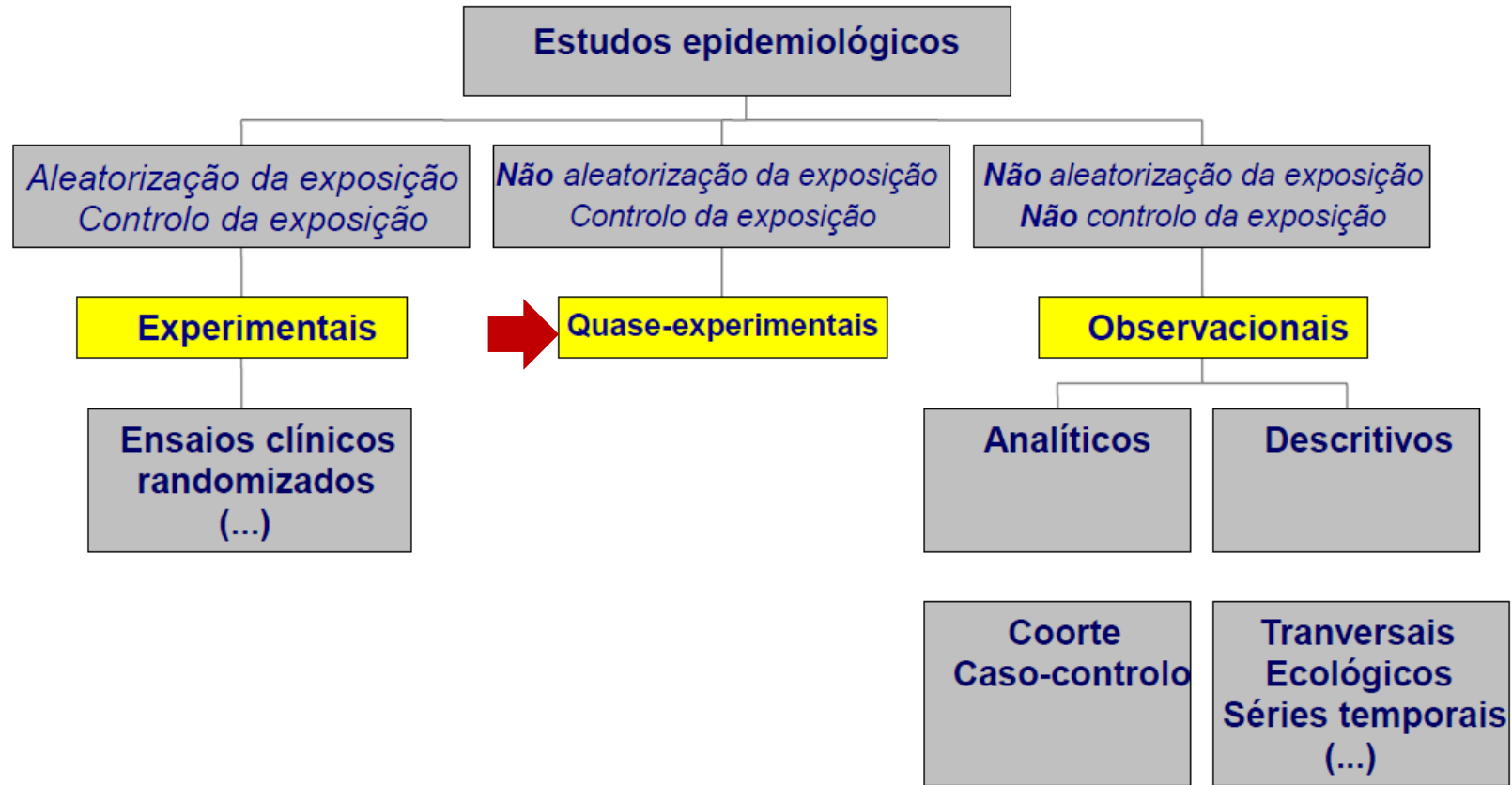


t_0



t_0

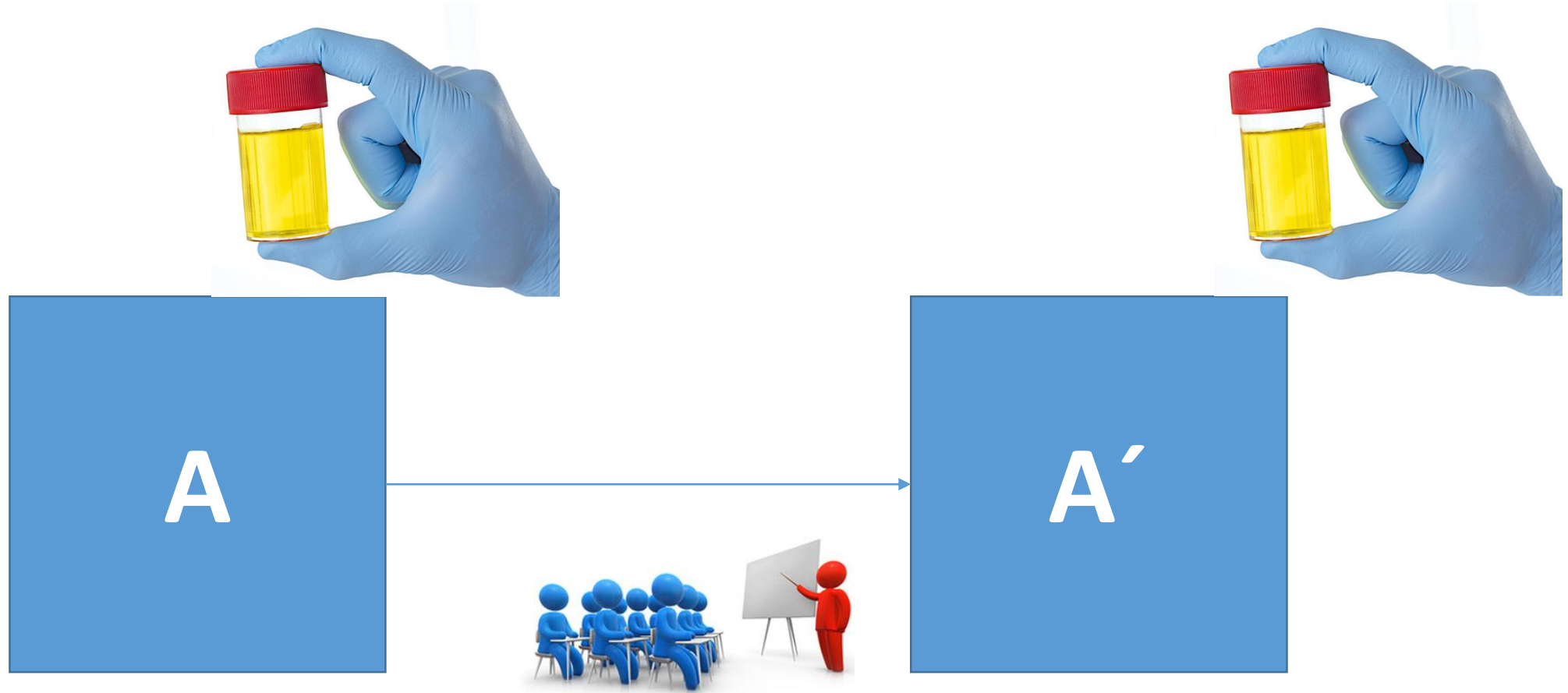






- # Avaliação de intervenções
- # Causalidade intervenção & outcome

#1





Estudos clínicos

Bases de investigação clínica para médicos

Firmino Machado, *MD, MSc Statistics, PhDc*

e: firmينو.firminomachado@gmail.com; t: 910961236

f: www.facebook.com/speedstatistics

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