

Projeto de Pesquisa: procedimentos

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Objetivos da aula

Qual a relação entre a pergunta de pesquisa e o procedimento?

Quem determina os procedimentos a serem utilizados?

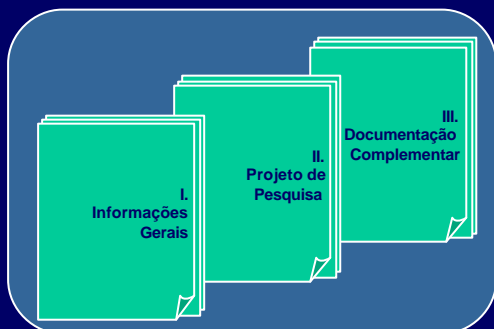
Quais são os itens necessários para definir um procedimento?

Quando é necessário o placebo e como descrevê-lo?

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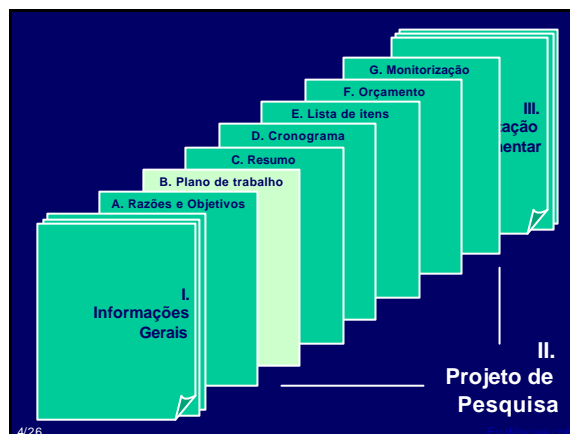
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Divisões do Projeto



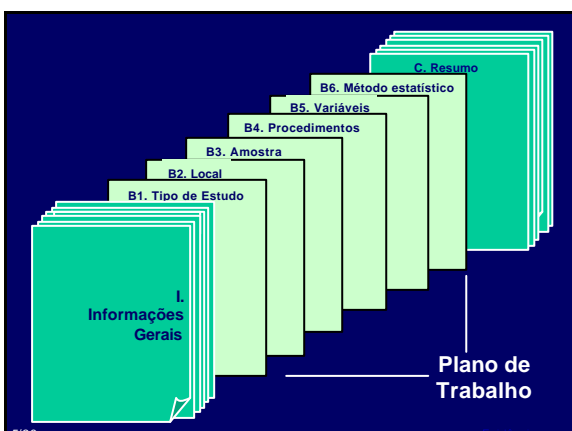
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O que é o procedimento?

Intervenção

(Medicamento, Cirurgia, Reabilitação, Programa educacional)

Teste diagnóstico

(anamnese, exame físico, exames complementares)

Exposição

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Comparação



O ponto chave!

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Qual a relação entre a pergunta da pesquisa e os procedimentos?



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O que é o procedimento?



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Quem determina os procedimentos a serem utilizados?



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B4. Procedimentos

Diagnóstico
Padrão Ouro
Teste diagnóstico

Comparação independente e cega

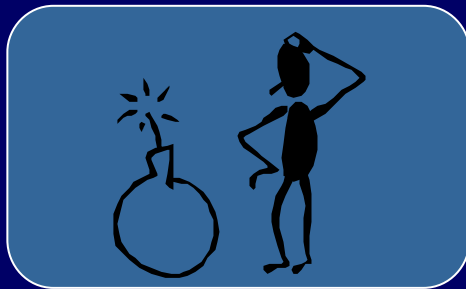
Tratamento
Grupo Experimental
Grupo Controle

Randomização e mascaramento

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Quem determina os procedimentos a serem utilizados?



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Quais são os itens necessários para descrever o procedimento?

Descrição detalhada

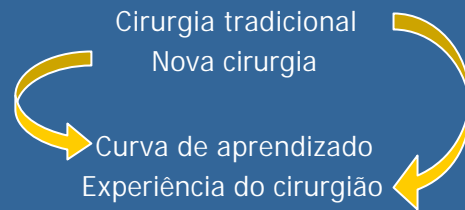
Medicamento

Droga, dose, via de administração, concentração, duração do tratamento; fabricante, cidade, lote.

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Intervenção na pesquisa em cirurgia



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Quando é necessário o placebo?

Como descrevê-lo?

Não temos uma droga eficaz

Não temos uma droga padrão

Cor
Tamanho
Forma
Textura
Número
Sabor

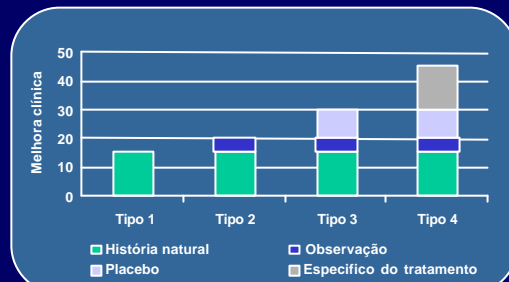
Idênticas as do princípio ativo

Simulação

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Efeito da intervenção



Fletcher RH, Fletcher SW, Wagner EH. Clinical Epidemiology 3th ed. Baltimore: Williams & Wilkins, 1996.

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Métodos de randomização



Pocock ST. Clinical trials: a practical approach. Chichester: Wiley; 1983.

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Métodos de mascaramento



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Métodos de randomização

Registro dos pacientes

Envelopes selados

Duplo-cego

Central de randomização

Preparando a lista de randomização

Randomização simples

Randomização por permuta de blocos

Randomização estratificada

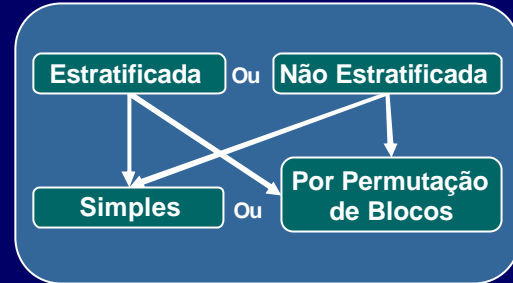
Randomização assimétrica

Pocock ST. Clinical trials: a practical approach. Chichester: Wiley; 1983.

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Randomização



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Exemplos de descrição



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PRISMS (Prevention of Relapses and Disability by Interferon-1a Subcutaneously in Multiple Sclerosis) Study Group. Randomised double-blind placebo-controlled study of interferon-1a in relapsing/remitting multiple sclerosis. Lancet. 1998 Nov 7;352:1498-504.

Question

In patients with relapsing-remitting multiple sclerosis (MS), does interferon-1a reduce the rate and severity of relapse?

Design

Randomized, double-blind, placebo-controlled trial with 2-year follow-up

Intervention

Patients were assigned to subcutaneous interferon-1a (Rebif, 6 million IU (22 µg) 3 times/wk ($n = 189$) or 12 million IU (44 µg) 3 times/wk ($n = 184$), or placebo ($n = 187$).

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The UK Small Aneurysm Trial Participants. Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. Lancet. 1998 Nov 21; 352:1649-55.

Question

In patients with small abdominal aortic aneurysms does early elective open surgical repair reduce mortality better than regular ultrasonographic surveillance of aortic diameter?

Design

Randomized, unblinded, controlled trial with up to 7 years of follow-up (mean 4.6 y).

Setting

93 hospitals in the United Kingdom.

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The UK Small Aneurysm Trial Participants. Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. Lancet. 1998 Nov 21; 352:1649-55.

Intervention

Patients were allocated to early surgery ($n = 563$) or ultrasonographic surveillance of the aneurysm diameter ($n = 527$). Surgery was done according to normal local procedures. In the surveillance group, patients with aneurysms 4.0 to 4.9 cm were seen every 6 months, and those with aneurysms 5.0 to 5.5 cm were seen every 3 months; elective surgical repair was recommended to patients if the aneurysm diameter was > 5.5 cm, the growth rate was > 1 cm/y, the aneurysm became tender, or iliac or thoracic repair was needed.

Evidence-Based Medicine May/June 1999 Volume 4 Number 3

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Kearon C, Gent M, Hirsh J, et al. A comparison of three months of anticoagulation with extended anticoagulation for a first episode of idiopathic venous thromboembolism. N Engl J Med. 1999 Mar 25;340:901-7.

Question

In patients who have had a first episode of idiopathic venous thromboembolism (VTE), will extended prophylaxis with warfarin reduce the rate of recurrence of VTE (deep venous thrombosis [DVT] and pulmonary embolism [PE])?

Design

Randomized, double-blind, placebo-controlled trial.

Setting

15 centers in North America.

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Kearon C, Gent M, Hirsh J, et al. A comparison of three months of anticoagulation with extended anticoagulation for a first episode of idiopathic venous thromboembolism. N Engl J Med. 1999 Mar 25;340:901-7.

Intervention

79 patients were allocated to warfarin with dose adjustments to maintain an international normalized ratio (INR) of 2.0 to 3.0, and 83 patients were allocated to placebo with sham dose adjustments.

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O aluno bem sucedido:

Entender qual a relação entre a pergunta de pesquisa e o procedimento;

Saber quem determina os procedimentos a serem utilizadas;

Entender quais são os itens necessários para definir um procedimento?

Saber quando é necessário o placebo e como descrevê-lo?

Saber qual o número de intervenções em um estudo fatorial?

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