

Clinical Trial Analysis

There are three ways to present the benefits of a clinical trial with a treatment group and a placebo group. 1) Absolute risk reduction. 2) Relative risk reduction. 3) Number needed to treat.

A case in point. What is the benefit of a cholesterol-lowering drug on the risk of coronary heart disease? The results of a landmark study presented to the American Heart Association in 1995 said "People with high cholesterol can rapidly reduce their risk of death by 22% by taking a widely prescribed drug called pravastatin sodium." As with most clinical trials, the benefit was reported as a relative risk reduction. So what did the 22% reduction mean? According to the author of the book sourced below, most people would think, based on surveys, it means that 220 people out of 1,000 could prevent a heart attack by taking the drug. However, that is not true.

The following data was presented for the 5-year trial.

Treatment	Deaths/1,000 People
Drug	32
Placebo	41

The results of the risk analysis are presented below. The absolute risk of death is reduced by only 0.90%. And 111 people would have to take the drug for 5 years to prevent 1 death.

Source: Calculated Risks: How to Know When Numbers Deceive You, by Gerd Gigerenzer, 2002, pp. 34-35.

Terms

TrNum - Number of people in the treatment group.

TrCases - Number of people in the treatment group who died or caught the disease.

PINum - Number of people in the placebo group.

PICases - Number of people in the placebo group who died or caught the disease.

%TrRisk - Percent of people in the treatment group who died or caught the disease.

%PIRisk - Percent of people in the placebo group who died or caught the disease.

%ABS RR - Percent absolute risk reduction (%PIRisk minus %TrRisk).

%Rel RR - Percent relative risk reduction ($\Delta\%$ TrRisk of PIRisk).

NNT - Number of people needed to treat to prevent one death or one person catching the disease ($1/((\%ABS\ RR)/100)$).

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October 3, 2021
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TrNum: 1000
TrCases: 32

PINum: 1000
PICases: 41

%TrRisk: 3.200
%PIRisk: 4.100

%ABS RR: 0.900
%Rel RR: 21.951

NNT: 111

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October 3, 2021
4:44:05 PM

Data from the FDA
Briefing Document

Pfizer-BioNTech
Covid-19 Vaccine
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TrNum: 19965
TrCases: 9

PINum: 20172
PICases: 169

%TrRisk: 0.045
%PIRisk: 0.838

%ABS RR: 0.793
%Rel RR: 94.619

NNT: 126