The concept of blinding in clinical trials

Introduction

Blinding is a procedure in which one or more parties in a trial are kept unaware of which treatment arms participants have been assigned to, in other words, which treatment was received. Blinding is an important aspect of any trial done in order to avoid and prevent conscious or unconscious bias in the design and execution of a clinical trial.

Blinding to avoid bias

The different parties involved in a clinical trial are all possible sources of bias, including:

- The patient being treated,
- The clinical staff administering the treatment,
- The physician assessing the treatment,
- The team interpreting the results.

All these parties can be blinded to ensure objectivity.

Types of blinding

A clinical trial is called single blind when only one party is blinded, usually the participants. If both participants and study staff are blinded, it is called a double blind study. Triple blinded studies also extend blinding to the data analysts. A trial in which no blinding is used and all parties are aware of the treatment groups is called open label or unblinded.

Table listing the different types of blinding

Type	Description
Unblinded or open label	All parties are aware of the treatment the participant receives
Single blind or single-masked	Only the participant is unaware of the treatment they receive
Double blind or double-masked	The participant and the clinicians / data collectors are unaware of the treatment the participant receives
Triple blind	Participant, clinicians / data collectors and outcome adjudicators / data analysts are all unaware of the treatment the participant receives

Unblinding is the disclosure to the participant and/or study team of which treatment the participant received during the trial. The process of unblinding is planned and included in the study protocol. Unblinding a trial is a necessary process to protect participants in the event of medical or safety reasons. There is also a defined process to ‘break the blind’ of a single participant when required.

Attachments

- Presentation: Blinding in Clinical Trials
  Size: 201,888 bytes, Format: .pptx
  This presentation provides more information about the concept of blinding in clinical trials.

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