Special populations in clinical studies

Introduction

A **clinical trial** is any investigation of one or more medicines in humans. The objective of such trials is to confirm the medicine’s safety (how well it is tolerated) and/or efficacy (how well it works).

Some groups in the general population may require special study. This may be because:

- there are particular risks or benefits that need special attention for certain populations, or
- a different dose or treatment schedule may be needed.

This article gives examples of these special populations and the unique considerations that are relevant to them when conducting clinical studies.

Clinical studies in elderly people

The use of medicines in this population requires special consideration due to the frequent occurrence of underlying diseases, use of other medicines at the same time and the consequent risk of medicines interaction.

Clinical studies in patients with impaired excretion

People who may have difficulty removing the medicine from their body, due to kidney or liver problems.

Clinical studies in pregnant women

In general, pregnant women should be excluded from clinical trials where the medicine is not intended for use in pregnancy. If a woman becomes pregnant while receiving a medicine, treatment should generally be stopped (if this can be done safely).

For clinical trials that include pregnant women because the medicine is intended for use during pregnancy:

- studies into reproductive toxicity is routine. However, special attention must be paid to these studies before pregnant women are included in clinical trials, and
- it is very important to follow up on the pregnancy, the foetus, and the child.

Clinical studies in breastfeeding women

When breastfeeding mothers are taking part in clinical trials, their children should be monitored for the effects of the medicine. In some cases, the medicine (or its metabolites) will be excreted into human milk and this should be examined.

Clinical studies in children

Clinical trials involving children are necessary in order to improve the treatments available to them. Children represent a vulnerable population – they have developmental, physiological, and psychological differences from adults.

Ages are defined in completed days, months, or years:

- preterm newborn infants
- term newborn infants (0 to 27 days)
- infants and toddlers (28 days to 23 months)

- children (2 to 11 years)
- adolescents (12 to 16/18 years, depending on region)

Clinical studies in ethnic sub-groups

Although ethnic differences among populations may cause differences in a medicine’s safety, efficacy, dosage, or treatment schedule, many medicines do have comparable characteristics and effects across regions. The Regulatory Authority or the trial sponsor may be concerned that differences in ethnic factors could alter the efficacy or safety of the medicine in the population in the new region.

Attachments

- Fact Sheet: Special Populations in Clinical Studies

  Size: 104,391 bytes, Format: .docx

  Special populations are subgroups of patients that require special treatment in clinical studies. This factsheet provides more information on these special populations.

- Presentation: Special Populations

  Size: 133,218 bytes, Format: .pptx

  Special populations are subgroups of patients that require special treatment in clinical studies. This presentation describes these special populations