International Standard

ISO 11249

Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies

Dispositif intra-utérin au cuivre à but contraceptif — Recommandations relatives à la méthodologie, la réalisation, l'analyse et l'interprétation des résultats des études cliniques

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 11249:2018), which has been technically revised.

The main changes are as follows:

— this document has been updated for the trial design to match the new requirements of a single arm study.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The clinical study guidance given in this document is intended to help in the design, execution, analysis, and interpretation of clinical studies conducted in accordance with the requirements of ISO 7439.

Intrauterine devices (IUD) are highly effective at preventing pregnancy. A new device aims at maintaining or improving the efficacy of intrauterine contraception and/or reducing the side effects associated with IUDs, such as excessive menstrual bleeding. Trials evaluating new or modified IUDs should be conducted to the highest standards, and this guidance will help those preparing for an IUD trial.

This document should be read in conjunction with ISO 14155.

It is based on the structure and content of a clinical investigation plan (CIP) as described in ISO 14155 to assist in the writing of a CIP and includes sections of the CIP that are of special relevance to IUD trials.

This document also draws on the experience gained in preparing the Cochrane systematic review of trials of copper-containing IUDs, which has been used to inform the updating of the WHO/UNFPA Specification for TCu380A IUD.

Clinical studies are also subject to local regulations and, in most countries, might require prior approval from the local regulatory body.

This document helps to ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results, and to assist sponsors, monitors, investigators, ethics committees or regulatory authorities.

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Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies

IMPORTANT — Persons designing, running, and analysing clinical studies of new IUDs shall be familiar with all relevant standards for research designed to protect the rights, safety and well-being of human participants.

1 Scope

This document provides guidance on the design and conduct of clinical studies to determine the performance characteristics of new intrauterine devices. It also provides advice on the analysis of data when the study is completed, as well as interpretation of these results by manufacturers, researchers and regulatory bodies.

Certain clinical trial concerns are not addressed in this document, including participant compensation, confidentiality of participants and their records, use of local ethics committees, etc. These and many other clinical trial design issues are covered in great detail in ISO 14155.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
adverse device effect
ADE
adverse event (3.2) related to the use of a *medical device* (3.21)

Note 1 to entry: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any *malfunction* (3.20) of the medical device.

Note 2 to entry: This includes any event that is a result of a use error or intentional misuse.

3.2
adverse event
AE
any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in *participants* (3.29), users or other persons whether or not related to the *investigational device* (3.19)

Note 1 to entry: This includes events related to the investigational device.

Note 2 to entry: This includes events related to the procedures involved.

Note 3 to entry: For users or other persons, this is restricted to events related to the investigational device.

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