Post-authorization surveillance study comparing the efficacy and safety of Medabon (mifepristone/misoprostol) to historical data for early pregnancy termination (Medabon PASS)

First published: 18/02/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5783

Study ID

22392

DARWIN EU® study

No

Study countries

- ☐ Sweden
- ☐ United Kingdom

Study description

This is an open-label, non-interventional, prospective, observational, post-authorization study of the outcomes and safety associated with the use of Medabon for the medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea. This study is designed to obtain descriptive information on the safety and efficacy of Medabon in women undergoing termination of early pregnancy, and to evaluate and compare the emergency evacuation rate, continuing pregnancy rate and requirement for surgical intervention to the historical rates for this combination treatment. Subjects requesting medical abortion for which treatment with mifepristone/misoprostol is medically appropriate will be treated with Medabon per institutional practice and according to the European Summary of Product Characteristics, and followed for at least 14 days for treatment outcome, adverse events, and the requirement for other subsequent interventional treatment.

Study status

Finalised

Research institutions and networks

Institutions

Karolinska University Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Juliette Omtzigt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2014

Actual: 01/03/2014

Study start date

Planned: 01/05/2014

Actual: 01/05/2015

Data analysis start date

Actual: 04/07/2017

Date of final study report

Planned: 07/11/2017

Actual: 07/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sun Pharmaceutical Industries Europe B.V.

Study protocol

Medabon Pass Protocol_19.08.13.pdf(1.74 MB)

PASS-001 Protocol Erratum.pdf(283.23 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To collect descriptive outcome data on the rate of incomplete abortion and continuing pregnancy, as well as the rate of adverse events related to the use of Medabon, in women requesting medical abortion with 63 days or less of gestation, as an additional pharmacovigilance measure in the risk management strategy for Medabon in Europe.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open-label, non-interventional, prospective, observational, post-authorisation study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

MIFEPRISTONE

MISOPROSTOL

Medical condition to be studied

Abortion induced

Population studied

Short description of the study population

Consecutively treated pregnant women with 63 days or less of gestation, requesting abortion and eligible for legal termination of pregnancy who have received Medabon per institutional practice and according to the European SPC, who are not participating in another interventional trial, and who are able to provide written informed consent.

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

The primary variable is the rate of incomplete abortion and continuing pregnancy at the time of the follow-up visit (10 to 14 days after the administration of mifepristone), the requirement for subsequent surgical evacuation, and the requirement for emergency evacuation due tohaemorrhage or other reasons. Secondary outcome variables include the incidence of AEs related to Medabon, and the necessity for additional medical treatment related to the termination of early pregnancy, such as the use of antibiotics to treat genital infections.

Data analysis plan

Frequency of AEs, SAEs and outcome variables will be summarized by body system, preferred term, and relationship to Medabon.On reaching 500 subjects, descriptive statistics and data listings will be used to summarize the data for the purposes of review by the sponsor. Adequacy of the risk management strategy for Medabon in Europe and the impact of risk management interventions will be assessedthroughout the study. On completion of the study, the final study report and Risk Management Plan for Medabon in Europe will be provided to the EMA.

Documents

Study results

CSR Ver 1.0 Abstract.pdf(102.69 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Post-authorisation surveillance study to assess the efficacy and safety of Medabon (Mifepristone/Misoprostol) for early pregnancy termination

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown