An escalating single oral dose trial investigating the safety, tolerance, pharmacokinetics and pharmacodynamics of orally administered Org 201745-0 in healthy sterilized women with normal ovulatory cycles

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The objectives are:1. To investigate the tolerability and safety of Org 201745-0 following single dose oral administration of six (tentative) escalating doses.2. To investigate the single dose pharmacokinetics of Org 201745-0, speed of absorption...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30881

Source
ToetsingOnline

Brief title
Single oral dose of Org 201745-0

Condition

- Other condition

Synonym
birth control, contraception

Health condition

anticonceptie

Research involving

Human

Sponsors and support

Primary sponsor: Akzo Nobel (Organon)Orion Pharma
Source(s) of monetary or material Support: sponsor

Intervention

Keyword: contraception, pharmacokinetics/dynamics, safety/tolerance

Outcome measures

Primary outcome

safety

tolerability

pharmacokinetics

pharmacodynamics

effect on ovulation

Secondary outcome

NA

Study description

Background summary

Org 201745-0 is developed for use as female contraception suitable for once a week administration

Study objective

The objectives are:

1. To investigate the tolerability and safety of Org 201745-0 following single dose oral administration of six (tentative) escalating doses.
2. To investigate the single dose pharmacokinetics of Org 201745-0, speed of absorption and secretion following single dose oral administration.
3. To investigate the pharmacodynamic effects of Org 201745-0 following single dose oral administration and to explore and, if possible, identify the major metabolites of Org 201745-0 in plasma and urine.

Study design

A maximum of 6 groups of 8 healthy female volunteers will participate in this study. The study consists of a medical screening, 1 admission period of 4 days, 17 short visits and finally a follow up.

Intervention

Group study drug or placebo
1 0,1 mg
2 0,3 mg
3 1,0 mg
4 3,0 mg
5 9,0 mg
6 20 mg

Dosis can be adapted based on the obtained interim study results.

Study burden and risks

The volunteers are during the course of the studyunder continious medical care of kendle staff. The starting dose is low and determined based on pre-clinical data. Furthermore, if needed the dosing schedule can be adapted.

Contacts

Public
Akzo Nobel (Organon)Orion Pharma

molenstraat 110
5340 BH
Nederland
Scientific
Akzo Nobel (Organon)Orion Pharma

molenstraat 110

5340 BH
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Healthy sterilized females with normal ovulatory cycles (i.e. a mean cycle length between 24 and 35 days and an intra-individual variation of plus or minus 3 days, but never outside the 24-35 days range.)
- Age between 18-50 years inclusive at the time of the first dosing administration.
- BMI 18.0-30.0 kg/m2 (extremes included).
- Good physical and mental health
- Ability and willingness to sign the Informed Consent Form prior to screening evaluations.

Exclusion criteria

• Contradictions for contraceptive steriods;
• History of trombosis or an ilness related to trombosis;
• an elevated risk of getting trombosis;
• History of drugs and/or alcohol abuse;
• Surgary within the last 3 months;
• use of medication within 14 days prior to study start (exeption of ibuprofen);
• if you participated in another trial within 3 months before the start of this study;
• if you donated blood within 3 months before the start of the study;
• if you are hepatitis B, C or HIV positive;
• if you are not suitable according to the principal investigator to participate in this trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	01-05-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	11-09-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	25-09-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-001111-37-NL
CCMO	NL17070.040.07