Een fase 0 onderzoek in mensen, waarin de farmacokinetiek van 14C gemerkte microdoseringen van [14C] ORG 201745 0, [14C]-ORG 244378-0 en [14C]-ORG 245021-0 bestudeerd wordt na orale toediening aan postmenopauzale vrouwelijke vrijwilligers

Gepubliceerd: 16-11-2007 Laatst bijgewerkt: 10-05-2024

1)To assess the preliminary pharmacokinetics of [14C]-Org 201745, [14C] Org 244378 and [14C] Org 245021 when administered as a sub-therapeutic dose by the oral route to healthy post-menopausal female volunteers.2) To evaluate the safety and...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Overige aandoening
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON31864

Bron
ToetsingOnline

Verkorte titel
[14C]-Org 201745, [14C]-Org 244378 en [14C]-Org 245021 Microdose Studie

Aandoening

- Overige aandoening

Synoniemen aandoening
anticonceptie, voorbehoedsmiddel

Aandoening

anticonceptie

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Organon Nederland BV
Overige ondersteuning: 4e geldstroom

Onderzoeksproduct en/of interventie

Trefwoord: AMS, microdosis, progesteron

Uitkomstmaten

Primaire uitkomstmaten

Pharmacokinetics : plasma drug concentrations; pharmacokinetic parameters in

plasma: Cmax, Tmax, AUC0-inf, t1/2; to perform pharmacokinetic analysis of

urine samples will be decided later after analysis of plasma samples

Safety : adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination.

Secundaire uitkomstmaten

none

Toelichting onderzoek

Achtergrond van het onderzoek

Currently marketed female contraceptives consist of a steroidal progestagenic compound, either combined with a steroidal estrogenic compound or given as a progesterone only product. Due to their steroidal nature, these compounds, and their metabolites, are often not specific for either the progesterone receptor or the estrogen receptor. It is thought that part of the undesirable side-effects observed with the use of current contraceptives is due to

inappropriate agonism or antagonism of the androgenic, mineralocorticoid or glucocorticoid receptors. This results in undesired effects on carbohydrate metabolism, hepatic function, lipid metabolism and thyroid function. In addition, estrogen-related side effects are cardiovascular effects secondary to hemostatic disturbance.
Org 201745-0, Org 244378-0 and Org 245021-0 are potent, metabolically stable, orally active non-steroidal selective progestagens with high selectivity for the progesterone receptor which are being developed as an estrogen-free female oral contraceptive suitable for once-a-week administration.

Doel van het onderzoek

1)To assess the preliminary pharmacokinetics of [14C]-Org 201745, [14C] Org 244378 and [14C] Org 245021 when administered as a sub-therapeutic dose by the oral route to healthy post-menopausal female volunteers.

2) To evaluate the safety and tolerability of a single oral administration of [14C-Org 201745, [14C] Org 244378 and [14C]-Org 245021 to healthy post-menopausal female volunteers

Onderzoeksopzet

a phase 0, open label, single oral dose study in post-menopausal female subjects with the compounds [14C]-Org 201745, [14C] Org 244378 and [14C]-Org 245021; each compound will be administered as a sub-therapeutic dose to 6 female subjects

Onderzoeksproduct en/of interventie

[14C]-Org 201745, [14C]-Org 244378 and [14C]-Org 245021 microdose

Inschatting van belasting en risico

As ORG 244378-0 en ORG 245021-0 will be administered to man for the first time in this study, adverse effects in man have not been reported up to now. The amount of study drug that is administered in this study is less than 1/100 th of the dose at which an effect is expected in the human body. With this *micro dose* the chance of unfavorable effects on your health may be considered minimal.

The two compounds have not been previously studied in humans. Safety studies conducted in rats demonstrated that the two compounds were well tolerated at a dose 1000-fold higher than the intended human microdose in this study.

In studies conducted in rats with ORG 244378-0 the following changes were observed: increased weight, red blood cell distribution width, total protein,

cholesterol and triglycerides in blood.
In studies conducted in rats with ORG 245021-0 the following changes were observed: slight increased weigth and increased level of triglycerides.

ORG 201745-0 has been administered to man recently for the first time in doses from 0.1 to 1 mg. The results from this ongoing study show that ORG 201745-0 can be administered to man safely and is well-tolerated.

Contactpersonen

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Wetenschappelijk

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Nederland

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

45-70 jaar
sinds 18 maanden geen mentruaties

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

relevant ziektes in de voorgeschiedenis

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-12-2007
Aantal proefpersonen:	18
Type:	Werkelijke startdatum

In onderzoek gebruikte producten en hulpmiddelen

Soort:	Geneesmiddel
Merknaam:	NAP
Generieke naam:	NAP

Ethische beoordeling

Goedgekeurd WMO Datum:	16-11-2007
Soort:	Eerste indiening
Toetsingscommissie:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Goedgekeurd WMO Datum:	23-11-2007
Soort:	Eerste indiening
Toetsingscommissie:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
EudraCT	EUCTR2007-005740-25-NL
CCMO	NL20522.056.07