TREATMENT ALTERNATIVES FOR SUBFERTILE WOMEN WITH CLASS II ANOVULATION NOT CONCEIVING AFTER SIX OVULATORY CYCLES WITH CLOMIPHENE CITRATE

Published: 10-10-2008
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The purpose of this study is to assess the effectiveness of extended treatment with CC compared to treatment with gonadotropins and/or the use of intra-uterine insemination (IUI), in patients who had six ovulatory cycles after CC, but did not...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON41546

Source
ToetsingOnline

Brief title
treatment after six ovulatory cycles with clomipheen

Condition

- Sexual function and fertility disorders

Synonym
anovulation, subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: clomipheen citrate, conception, gonadotrophin, infertility, insemination, ovulation

Outcome measures

Primary outcome

Pregnancy leading to live birth.

Secondary outcome

clinical pregnancy

miscarriage

multipel pregnancy

occurence of ovulation

Study description

Background summary

Ovulation induction with Clomiphene citrate (CC) is the first line of treatment in women with WHO class II anovulation. Whereas almost 80% of these patients ovulate after CC, only 40 to 50% conceive. When unsuccessful in conception, treatment can be proceeded with gonadotropins. CC treatment is associated with a 8% risk of multiple gestation, whereas treatment with gonadotropins is associated with a risk of 30-40 %. At present, it is unclear for how many cycles ovulation induction with CC should be repeated, and when to switch to ovulation induction with gonadotropins and/or add of intra-uterine insemination.

Study objective

The purpose of this study is to assess the effectiveness of extended treatment with CC compared to treatment with gonadotropins and/or the use of intra-uterine insemination (IUI), in patients who had six ovulatory cycles

after CC, but did not conceive.

Study design

Randomized multicenter controlled trial

Intervention

Patients will be randomly allocated to four treatment arms: extended CC treatment for 6 months, ovulation induction with gonadotropins for 6 months, extended CC treatment with IUI for 6 months and ovulation induction with gonadotropins with IUI for 6 months

Study burden and risks

As we compare strategies that are already applied in current practice, no additional risks or burdens are expected from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients with six ovulatory cycles after CC treatment and no conception. Ovulation is assessed by a midluteal progesterone (> 16 nmol/l), basal temperature curve, detection of LH surge or history, depending on the local protocol.
• All patients have normal serum FSH (<10 IU/l), E2 (> 80 pmol/l), prolactin (0,05 - 0,80 IU/l) and thyroid-stimulating hormone (0,4 - 4,0 mU/l).
• All women have patent Fallopian tubes, proven by hysterosalpingography (HSG), a negative Chlamydia antibody titre (CAT) or diagnostic laparoscopy combined with tubal testing (DLS and TT), depending on the local protocol.
• The partners have normal semen parameters according to the modified criteria of the World Health Organization (1999).
• Age between 18 and 40 years.

Exclusion criteria

• Patients who have previously been treated with gonadotropins or IVF are excluded.
• Patients are excluded if they have intolerable symptoms when treated with CC like hot flashes affecting daily function, headaches, vision changes, and depression
• Patients are excluded if they remain anovulatory on CC 150 mg.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	660
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	clomid
Generic name:	clomiphene citrate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	pregnyl
Generic name:	human choriongonadotrophin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	puregon
Generic name:	follitropin beta
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-10-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-10-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	11-12-2008
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-03-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	13-03-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-05-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	05-06-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-06-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-07-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	03-11-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	10-11-2009
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	19-11-2009
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	13-04-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-06-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-06-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	05-11-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-12-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-01-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	19-07-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-11-2011
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	05-07-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	26-07-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-08-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-08-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-10-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-10-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-12-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-01-2013
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	12-02-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	25-02-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-02-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	13-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	15-04-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-04-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-10-2013
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-05-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	15-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-05-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-06-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	EUCTR2008-006171-73-NL
CCMO	NL25324.044.08
Other	TC = 1449 (NTR)