SUMMER-study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26205

Source
Nationaal Trial Register

Brief title
SUMMER

Health condition

Infertility, subfertility, male infertility, nutritional supplements

Sponsors and support

Primary sponsor: Radboud University Medical Centre
Department of Obstetrics and Gynaecology
PO Box 9101 6500HB Nijmegen
The Netherlands
Source(s) of monetary or material Support: Goodlife Fertility B.V.
Hollandse Hout 239
8244 GJ Lelystad

Intervention

Outcome measures

Primary outcome

To test the hypothesis that the number of ongoing pregnancies (i.e. ≥12 weeks of gestation) will be improved by 7.5% in couples treated with Impryl® for infertility (IUI, IVF/ICSI or EM

setting).

Secondary outcome

Overall pregnancy rate. Time to pregnancy defined as both the time between a) start of intervention and reaching ongoing pregnancy, and as b) start of fertility treatment and reaching ongoing pregnancy. Change in semen parameters between baseline and 3 months intervention, based on pre-wash total motile sperm count (TMSC) from the subpopulation from Radboudumc and sites that deliver a pre-wash TMSC before IUI/IVF/ICSI. Number of miscarriages defined as a non-vital intra-uterine pregnancy before 16 weeks of gestation. Number of ongoing pregnancies above ≥ 20 weeks. Live birth rate defined as beyond 24 weeks of gestation, the birth of a living child. Live births will be reported within follow-up time of 15 months. Furthermore the following adverse events will be reported: gastro-intestinal problems such as reflux, obstipation, diarrhea, nausea or vomiting, furthermore loss of appetite, headache, dizziness, pruritus or skin rash.

Study description

Background summary

Rationale: Infertility is a worldwide problem and about 10%-15% of all couples will be affected by the inability to have children. In approximately 50% of infertile couples a male factor is involved. In the past decade, the role of oxidative stress on sperm has been researched thoroughly and found to be the problem in 30% to 80% of male infertility cases. Impryl® is a nutritional supplement which works on the metabolic system and regulation of oxidative stress by activating the one carbon cycle and therefore recycling of homocysteine.

Objective: To determine the effectiveness of nutritional supplement Impryl® in men of infertile couples on ongoing pregnancy rate, with or without assisted reproduction technology (ART).

Study design: Multicentre, randomised double blind placebo controlled clinical trial/superiority study.

Study population: All participants in this study are male adults, age 18-50 years, part of a couple that is diagnosed with infertility, unregarded the outcome of semen analysis. The couple will either start or is already started with fertility treatment, i.e. expectative management (EM, duration 6 months), intra-uterine insemination (IUI) with or without ovarian stimulation (mild ovarian hyperstimulation (MOH) or ovulation induction (OI)), either in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) treatment.

Intervention: Impryl® or placebo, with identical appearance one tablet each day for a total duration of 6 months. Intervention has to be consumed for at least 3 consecutive months before using semen for ART. In case of expectative management, patients can start directly

to conceive.

Main study parameters/endpoints: The primary outcome is the number of ongoing pregnancies ≥ 12 weeks. Secondary outcomes are change in semen parameters between baseline and 3 months intervention in IUI/IVF/ICSI group, based on (pre-wash) total motile sperm count (TMSC). Furthermore the occurrence of pregnancy, time to pregnancy, number of miscarriages, number of ongoing pregnancies ≥ 20 weeks and live birth rate are documented within the study period. The occurrence of adverse events will be reported.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Couples with infertility will receive standard fertility treatment, i.e. EM or ART. The risks and burden of participating in the trial are small. After a complete diagnostic work-up for infertility, the males will be randomised for use of either Impryl® or placebo. Impryl® is a food supplement already free available throughout Europe. Males need to take study medication one tablet each day for 6 months in total. For this study, we want to measure improvement of semen parameters after at least 3 months use of study medication. Performing a pre-wash TMSC is in Radboudumc standard procedure when semen is used for IUI or IVF/ICSI. However, at some sites there is only a post-wash TMSC available. Furthermore, in couples with EM performing a TMSC after 3 months is not standard care. We decided not to perform a semen analysis in the EM group due to the fact that improvement in fertility treatment from expectative management is not possible. Participants are required to collect study medication directly at their local hospital or at Radboudumc. At the start of taking study medication the couple is asked to fill in a questionnaire about their baseline characteristics. To asses lifestyle changes during intervention and amount of used study medication, every male will be asked each month (6 times in total) to fill in an online questionnaire. Every couple will receive a final questionnaire, 15 months after inclusion, about the outcome of fertility treatment and occurrence of pregnancy. If a women of a couple is pregnant there is one extra site visit to have an ultrasound at 12 weeks of pregnancy for determining the primary outcome. In conclusion, the burden and risks associated with participation in this trial can be considered negligible.

Study objective

To determine the effectiveness of nutritional supplement Impryl® on pregnancy rate in men of infertile couples, with or without medically assisted reproduction (MAR).

Study design

0 - 1 - 2 - 3 - 4 - 5 - 6 - 15 months

Intervention

nutritional supplement Impryl®

Contacts

Public
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Eligibility criteria

Inclusion criteria

Couples with failure to conceive for at least 12 months

Couples starting with EM or 1st/ 2nd/3rd cycle of IUI (with/without ovarian stimulation) or IVF/ICSI

Male with age 18-50 years

Female partner with age 18-43 years

Willing and able to give informed consent

Exclusion criteria

Planned or performed diagnostic testicular biopsy (TESE) or percutaneous epididymal sperm aspiration (PESA)

Ovulation induction (OI) without IUI

IVF for an absolute tubal factor

Embryo-transfers after cryopreservation

Known chromosomal abnormalities related to infertility

Known urological abnormality such as a varicocele

Use of other vitamin supplements

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	1200
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-06-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53075
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6367
NTR-old	NTR6551
CCMO	NL61414.091.17
OMON	NL-OMON53075

Study results