The impact of a nutritional supplement (Impryl®) on male fertility

Published: 12-10-2017
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To determine the effectiveness of nutritional supplement Impryl® in men of infertile couples on ongoing pregnancy rate, with or without assisted reproduction technology (ART).

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

Summary

ID

NL-OMON53075

Source
ToetsingOnline

Brief title
SUMMER-trial

Condition

- Sexual function and fertility disorders

Synonym
infertility, Male subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Goodlife in de vorm van een unrestricted grant; Onderzoeksstipendium van het Jeroen Bosch ziekenhuis (15.000 euro),Goodlife pharma

Intervention

Keyword: Male fertility, nutrition, ongoing pregnancy, supplement

Outcome measures

Primary outcome

Number of ongoing pregnancies, conceived in the time window between randomization up to and including month 6 of intervention use. Ongoing pregnancy is defined as a visible embryonic heartbeat at ultrasound from 10-12 weeks of gestation onwards.

Secondary outcome

Secondary outcomes are number of pregnancies conceived in the optimal intervention time window (i.e. between start of month 4 till the end of month 6), overall pregnancy number, 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. In a population of 80 patients, the DNA fragmentation in sperm cells will be assessed before intake of study medication and after 3 months of intake of either Impryl or placebo. The occurrence of adverse events will be reported.

Study description

Background summary

Infertility is a worldwide problem and about 10% 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 subfertility cases. Oxidative stress in the sperm cells can be measured with DNA fragmentation assays, these assay measure the level of DNA damage in the sperm cells. 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.

Study 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.

Intervention

Impryl® or placebo, with identical appearance one tablet each day for a total duration of 6 months. Patients can start directly to conceive or start with fertility treatment.

Study burden and risks

Couples with infertility will receive standard fertility treatment, i.e. EM or ART. The risks 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.

Patients included in the Jeroen Bosch hospital will have two extra visits to the hospital - upon inclusion and after 3 months - to hand over a semen sample for the assessment of DNA fragmentation. The riks of participation for these patients is low and the burden of participation for these patients is moderate.

The risks and burden associated with participation in this trial for all other patients (except Jeroen Bosch hospital) can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2018
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-02-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-07-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	30-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-05-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26205
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61414.091.17
OMON	NL-OMON26205