Choice Preclinical Gametes Study - Sperm Survival

Published: 28-04-2023
Last updated: 27-12-2024

The purpose of this preclinical study is to obtain a quantitative measurement about the survival of human sperm cells when in contact with the Choice device. This in order to study safety and biocompatibility of the materials used for the Choice...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51336

Source
ToetsingOnline

Brief title
Choice Sperm Survival Test

Condition

- Other condition

Synonym
Contraception & Fertility

Health condition

Anticonceptie

Sponsors and support

Primary sponsor: Choice B.V.
Source(s) of monetary or material Support: Choice B.V.

Intervention

Keyword: Anticonception, Preclinical, Sperm, Sterilisation

Outcome measures

Primary outcome

Spermcell count and survival (%)

Secondary outcome

If possible, motility (survival)

Study description

Background summary

The Choice device is intended to prevent pregnancy when closed, but also to facilitate pregnancy when opened. To facilitate pregnancy, the sperm cells should be able to move through the Choice device to reach the ovum in the ampulla of the fallopian tube. This can only be achieved when the sperm cells survive in the presence of the Choice device and the materials it is made of.

Study objective

The purpose of this preclinical study is to obtain a quantitative measurement about the survival of human sperm cells when in contact with the Choice device. This in order to study safety and biocompatibility of the materials used for the Choice device and to enhance the further development of Choice. When the materials used for the Choice device enable sperm to survive just as good as they normally would (without a Choice device present), this provides additional information about biocompatibility of the materials used.

Study design

In order to test the human sperm survival rates a routine semen analysis will be performed with focus on viability.
- Sperm count (number and percentage of survival)
- Motility (survival)
- Volume
- PH (optional)

In total 5 healthy male volunteers in the age 18-50 are requested to donate

sperm. These men will be asked to refrain from having sex or masturbation for 2-5 days before sample collection. Semen of those volunteers will be processed according the UMCU standard viability testing protocol (see below) with the addition of the Choice device in the Petri dish.
The sperm sample of the five volunteers will be divided into two petri dishes, which means they will be their own control group:
- Group A - semen sample without Choice Device (N = 5)
- Group B - semen sample with a (sterile) Choice Device (N=5)

In the event that one or more of the voluntary donors has a semen motility rate of less than 30 percent and/or zero spermatozoa this donor material must be replaced. Therewith the total number of voluntary donors could possibly exceed 5 so that in total 10 petri dishes with semen samples will be processed and counted (number of sperm cells per ml) in a so called Makler or Neubauer countingroom. After 24 hours an evaluation will be made of the number surviving (%) sperm cells in the same countingroom. Those 2 values: sperm cell count per ml and survival (%) before and after 24 hours will be the measurement of this study.

It is very important that the Choice Device that will be placed in the petri dishes is sterile as contamination has major impact on survival.

Study burden and risks

None.

Contacts

Public
Choice B.V.

Torenallee 20
Eindhoven 5617 BC
NL
Scientific
Choice B.V.

Torenallee 20
Eindhoven 5617 BC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Healthy male
Age 18-50
Volunteers to donate sperm

Exclusion criteria

Not willing to sign ICF

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2023
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO Date:	28-04-2023
Application type:	First submission
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
CCMO	NL81942.000.22