Why subfertile couples drop out

Published: 23-09-2014
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Primary Objective: To identify dropout rates at all stages of fertility care at the fertility centres of Isala in Zwolle, Erasmus MC in Rotterdam, Reinier de Graaf group in Voorburg, Elisabeth Twee Steden in Tilburg, the St Antonius Ziekenhuis in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON44890

Source
ToetsingOnline

Brief title
Drop out trial (DOT)

Condition

- Anxiety disorders and symptoms
- Reproductive tract disorders NEC
- Family issues

Synonym
discontinuation, drop out

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Merck,Stichting Onderzoek en Onderwijs Voortplantingsgeneeskunde Zwolle

Intervention

Keyword: Dropout, IVF, NON IVF, Subfertility

Outcome measures

Primary outcome

Dropout rates during fertility work-up, non-IVF treatment or IVF/ICSI

Secondary outcome

Reasons for drop-out

Patient satisfaction with received care

Demographic and psychological characteristics of the couples

Predictors of discontinuation of treatment

Study description

Background summary

Due to major advances in artificial reproductive technology (ART) treatments success rates, often presented as ongoing pregnancy rates or live birth rates, are increasing. Nowadays, pregnancy rates after IVF are comparable with natural conception rates per cycle. However, several studies have reported high dropout rates, varying from 23% up to 60%, during fertility treatment and from a clinicians point of view it can be stated that high dropout rates negatively affect the clinics performance. Drop out is defined as leaving the program for reasons other than pregnancy or heaving reached a point beyond which treatment is not useful anymore. In case a couple does not return to the clinic within 6 months during treatment or work up is also defined as drop out.

Studies have revealed that emotional, economic and physical burden of a fertility program can be a reason to drop out. These studies mostly involve couples that underwent IVF, although a few studies reported on couples dropping out on a waiting list for IVF and during fertility treatment in general.

Fourteen studies in the systematic review by Gameiro et al. published data on predictors for drop out, mainly on sociodemograpic and fertility treatment predictors. Only three studies published on psychosocial predictors such as anxiety, depressive symptoms and marital and relational problems. No

significant predictors were found to explain patient drop out, however in two third of the studies focussing on depression and ART an association was found. The authors came to the conclusion that more research needs to be done to fully understand drop out due to low power of the studies.

To be able to predict and eventually prevent drop out it is necessary to assess thoroughly the existence of possible prognostic factors that might generate drop out.

Study objective

Primary Objective:
To identify dropout rates at all stages of fertility care at the fertility centres of Isala in Zwolle, Erasmus MC in Rotterdam, Reinier de Graaf group in Voorburg, Elisabeth Twee Steden in Tilburg, the St Antonius Ziekenhuis in Nieuwegein, Maxima Medisch centrum in Veldhoven and Noordwest Ziekenhuis groep in Alkmaar/Den Helder.
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Secondary Objective(s):
• To investigate the reasons for drop out
• To examine patient satisfaction with received fertility care
• To identify the demographic characteristics of drop out patients
• To identify predictors for discontinuation

Study design

Setting: This prospective multi centre cohort study will be performed at the fertility centres of of Isala in Zwolle, Erasmus MC in Rotterdam, Reinier de Graaf group in Voorburg, Elisabeth Twee Steden in Tilburg, St Antonius Ziekenhuis te Nieuwegein, Maxima Medisch centrum te Veldhoven and Noordwest Ziekenhuis groep in Alkmaar/Den Helder.

Every new eligible patient and her partner will both be asked for informed consent to participate in this study at their first visit at the clinic during the intake by the treating doctor. After inclusion the couple will receive an e-mail link to a website based questionnaire which is entitled to the first questionnaire (Q1). From the intake onwards every couple will have their regular work up and/or treatment visits during which evaluation will take place using consecutive another questionnaire (Q2, Q3 or Q4). The first questionnaire will focus on psychological and socio-demographic questions, whereas the other questionnaires will address coping styles, depression and anxiety.
When pregnancy is achieved, patients are invited to fill in Q6, to evaluate the provided care. When treatment is stopped on medical advice, those patients are

excluded from any further follow up. Other patients are followed up as drop out after they have not showed up to the clinic for at least six months. Those patients are contacted to fill in the final questionnaire (Q5). This questionnaire will apart from FertiQol, SCREENIVF and MMQ also assess PCQ infertility as well as reasons of withdrawal.

Study burden and risks

No additional risks are expected. The only burden for the patients is that it will cost some extra of their time to fill in the questionnaire.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Female age between 18 and 44 years
• Couples with any type of subfertility referred to one of the 5 participating centres
• Both partners are willing and able to separately fill out the questionairres

Exclusion criteria

• Unable to read or speak the Dutch language
• Medical contra-indication for pregnancy
• Previous OFO, non IVF or IVF/ICSI cycles

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2015
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	04-12-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-01-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	18-04-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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
ClinicalTrials.gov	NCT02302781
CCMO	NL47393.075.14