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Impact of a psychological intervention in patients under assisted reproductive treatment (in vitro fertilisation [IVF]/intra-cytoplasmic sperm injection [ICSI])

Submission date
11/03/2009

Recruitment status
No longer recruiting

Registration date
11/05/2009

Overall study status
Completed

Last Edited
11/05/2009

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Grant no.: 325100-11375411

Study information

Scientific Title
Impact of a psychological intervention in patients under assisted reproductive treatment (in vitro fertilisation [IVF]/intra-cytoplasmic sperm injection [ICSI]): a prospective (longitudinal) blinded randomised experimental intervention study

Study objectives
1. A significant difference in psychological outcome is expected between groups. Specifically, it is assumed that the group with the psychological intervention will have better outcomes in terms of psychological functioning (quality of life and depression, suffering from infertility).
2. A difference in biomedical outcome is expected between groups. As above, it is assumed that the group in the psychological intervention condition will profit in terms of a higher chance of pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee of Bern (Switzerland) gave approval on the 22nd March 2007 (ref: KEK-BE 005/07)

Study design
Interventional multicentre prospective (longitudinal) blinded randomised experimental intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions
Psychological intervention versus a waiting control group.

Psychological intervention (fertility group intervention):
A combination of clarification and mastery techniques, based primarily on principles of cognitive behavioural therapy, clarification-oriented therapy and system therapy. The intervention consists of 10 weekly sessions organised according to 10 thematic blocks: a structured group /couple setting and a combination of educational and supportive therapeutic elements.

Waiting control group:
The control group is randomised to the waiting list control patients for 6 months. After this time they could participate in the intervention if they want.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Specific stress reactions:
1.1. Infertility distress questionnaire (Fragebogen zur infertilitätsbedingten Belastung [IBS]; 11 items)
1.2. Cognitions in infertility questionnaire (Kognitionen bei Infertilität [KINT]); 20 items)
2. Psychological functioning:
2.1. Centre for Epidemiologic Studies Depression Scale (CES-D); 20 items
2.2. German Inkongruenzfragebogen (K-INK); 23 items
3. Pregnancy rate

All primary and secondary outcome measures were assessed at baseline, after 5 weeks, at post-treatment (12 weeks after baseline), and at six-month follow-up.

Secondary outcome measures
1. Psychosocial conditions:
1.1. Demographic questionnaire (Socioeconomic Status [SES]; 14 items)
1.2. Relationship Assessment Scale (RAS); 7 items
1.3. Sozialer Support; 7 items
2. Coping, self-efficacy, emotion regulation:
2.1. Coping Inventory for Stressful Situations (CISS) short version; 19 items
2.2. Self-efficacy questionnaire (Selbstwirksamkeit [SWE]; 10 items)
2.3. Emotion Regulation (EMOREG); 26 items

All primary and secondary outcome measures were assessed at baseline, after 5 weeks, at post-treatment (12 weeks after baseline), and at six-month follow-up.

Overall study start date
01/06/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Written consent for this study as well as for the IVF/ICSI treatment are on hand
2. The patient is currently not in psychological treatment
3. The patient has an indication to an IVF/ICSI treatment
4. The patient is in reproductive age (maximal age is 42 years)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
A total of 120 participants

Key exclusion criteria
1. Inability to communicate
2. Fundamental contraindications to an IVF/ICSI treatment:
2.1. Acute/chronic infectious diseases: human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis
2.2. Severe psychiatric diseases: schizophrenia, severe depressive disorders
2.3. Acute/chronic addiction
2.4. Carrier of a severe genetic disease
2.5. Age of the female patient is greater than 42 years
3. Need of psychological or psychiatric treatment before or during the study
4. Not any more willing to participate in the study
5. Severe injuries to the protocol
6. Separation of the couple
7. Severe disease of one partner

Date of first enrolment
01/06/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Switzerland

Study participating centre
Institute of Psychology
Bern
Switzerland
3012

Sponsor information

Organisation
Swiss National Science Foundation (Switzerland)

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Sponsor type
Government

Website
http://www.snf.ch/D/Seiten/default.aspx

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Government

Funder Name
Swiss National Science Foundation (Switzerland) (grant ref: 325100-11375411)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration