Mentaal welzijn en kwaliteit van leven na insertie van een LNG-IUD versus een Cu-IUD. Een prospectieve studie.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22570

Source
NTR

Brief title
E-CHIQ study

Health condition

Cu-IUD
LNG-IUD
Mental well being
Quality of live
Koper spiraal
Mirena spiraal
Kyleena spiraal
Mentaal welzijn
Kwaliteit van leven

Sponsors and support

Primary sponsor: Titus Health Care
Source(s) of monetary or material Support: Titus Health Care B.V.
Kruisweg 647
2132 NC Hoofddorp

Intervention

Outcome measures

Primary outcome

rimary endpoint of this prospective cohort study is to determine whether or not a difference in mental well-being can be observed between patients receiving an LNG-IUD versus an Cu-IUD. The comparison will be made prior to and at the time of IUD insertion and at three, six and twelve months after IUD insertion.

Secondary outcome

Secondary outcomes that will be analysed involve overall quality of life, bleeding pattern, satisfaction with their IUD, reasons for discontinuation, sexual functioning and unintended pregnancy.

Study description

Background summary

The number of women looking for long acting reversible contraception (LARC) is on the rise in the Netherlands. The rise in the number of IUDs can predominantly be ascribed to the growing popularity of the levonorgestrel IUD (LNG-IUD). The promise of a reduction in the monthly amount of blood loss in the absence of systemic effects seems to be the most important reason for women to prefer a LNG-IUD over e.g. oral contraceptives or a Copper-IUD (Cu-IUD). Shortly after the report of the Rutgers stichting, a large prospective study regarding the physiological responses to stress in women using the LNG-IUD was published. This study showed that despite the low daily dose of levonorgestrel release by the LNG-IUD significant effects on basal heart rate and the release of cortisol are observed, disproving the common assumption that the LNG-IUD has little to no systemic influence. Therefore, as well as other hormonal contraceptives, LNG-IUD might have an effect on mental wellbeing and quality of life. Cu-IUDs have been available for decades for women looking for LARC and offer a true hormone free alternative to the LNG-IUD. Most comparative studies between LNG-IUD and Cu-IUD so far have focussed on bleeding patterns, efficacy as well discontinuation rates. So far, little notice has been paid on comparison of mental health or quality of life. The objective of this prospective cohort study is therefore to compare the effects of LNG-IUD versus Cu-IUD (T-Safe or Multi-Safe) on mental well-being and quality of life. Secundary outcomes that will be analysed involve overall quality of life, bleeding pattern, satisfaction with their IUD, reasons for discontinuation, sexual functioning and unintended pregnancy at 3, 6 and 12 months.

Study objective

The hypothesis of this study is that a difference in mental well-being can be observed after insertion of an LNG-IUD compared to Cu-IUD insertion.

Study design

The comparison with regard to the primary endpoint will be made prior to and at the time of IUD insertion and at three, six and twelve months after IUD insertion.

Intervention

women willing to participate in the study are requested to answer a web-based questionnaire prior to the IUD insertion, on the day of insertion as well as three, six and twelve months after insertion. Questions regard mental well-being, quality of life, bleeding pattern, satisfaction with their IUD, reasons for discontinuation and unintended pregnancy.

Contacts

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Eligibility criteria

Inclusion criteria

• Age; between 18 and 45 years

• Wish for LARC by means of a LNG-IUD or Cu-IUD for a minimum period of 12 months.

• Willing to fill out 5 questionnaires, taking 15 to 20 minutes per questionnaire.

• Access to internet and sufficient understanding of Dutch language.

• Willing to provide informed consent.

Exclusion criteria

• Cu-IUD insertion as emergency contraception.

• Patients with heavy bleeding pattern/problems or with a wish for less blood-loss.

• Patients with an Cu-IUD or LNG-IUD < 3 months prior to placement this IUD

• IUD insertion while being under general anaesthetics.

• IUD insertion within 6 weeks postpartum and 12 weeks after a caesarean are excluded.

• Contraindications according to the product leaflets.

• patients taking medication against a mental conditions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	420
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6797
NTR-old	NTR6983
Other	: ABR nummer 64587

Study results