Mental wellbeing and quality of life after insertion of a LNG-IUD or Cu-IUD. A randomized patient preference trial.

Published: 20-08-2018
Last updated: 12-04-2024

To compare the effects of LNG-IUD (Mirena® of Kyleena®) versus Cu-IUD (T-Safe® or Multi-Safe®) on mental well-being and quality of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48848

Source
ToetsingOnline

Brief title
Quality of life after LNG-IUD versus Cu-IUD (E-CHIQ study).

Condition

- Other condition
- Gonadotrophin and sex hormone changes

Synonym
well-being; quality of life

Health condition

anticonceptie

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: Titus Health care

Intervention

Keyword: Cu-IUD, LNG-IUD, Mental well being, Quality of live

Outcome measures

Primary outcome

Primary 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 at 3, 6 and 12 months.

Study description

Background summary

The number of women looking for long acting reversible contraception (LARC) is on the rise in the Netherlands. A recent report by the Dutch centre for sexual health over the period from 2012 till 2017 showed a substantial increase in the number of women under the age of 25 opting for an intra-uterine device (IUD) as contraceptive method of choice. 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. In the Dutch GP Guidelines (NHG) the T-Safe Cu380A and the Multiload IUD*s are the preferred Cu-IUD due their high efficacy and low discontinuation rates. The Multi-Safe IUD (generic Multiload IUD) is available since 2016 after the withdrawal of Multiload from the Dutch market. 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.

Study objective

To compare the effects of LNG-IUD (Mirena® of Kyleena®) versus Cu-IUD (T-Safe® or Multi-Safe®) on mental well-being and quality of life.

Study design

A randomized patient preference trial comparing mental wellbeing and quality of life after insertion of a LNG-IUD or Cu-IUD.

Intervention

Randomization between Cu-IUD or LNG-IUD. If a patient is not willing to be randomized she can participate in the parallel cohort study.

Study burden and risks

Given the fact that insertion of an IUD and the web-based questionnaires participating patients are not exposed to any risks or benefits. This study will hopefully result in improved counselling and thereby ultimately helping patients decide which IUD suits their personal situation best. The estimated total time that the questionnaires will take to fill in is approximately 15 to 20 minutes per questionnaire. So a total time investment of 75-100 minutes after completion of all five questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2018
Enrollment:	394
Type:	Actual

Ethics review

Approved WMO Date:	20-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL64587.048.18
Other	NTR - 6983