Re-Essure study

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1) Several symptoms will not improve after removal. 2) Symptoms are similar to other tubal occlusion methods

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29147

Bron
NTR

Aandoening

Essure, sterilization, implants, nickel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

symptom reduction at 12 months after removal.

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND: Increasing number of symptomatic women request for Essure removal. RESEARCH QUESTIONS: 1) Are symptoms reversed after Essure removal? 2) Are symptoms comparable to other tubal occlusion methods? HYPOTHESIS: 1) Several symptoms will not improve after removal. 2) Symptoms are similar to other tubal occlusion methods. STUDY

DESIGN: A prospective multicenter cohort study consisting of two parts STUDY POPULATION: 1) All women requesting for Essure removal. 2) Women who received any tubal occlusion method. FOLLOW-UP: 1) 2 times before, 3 and 12 months after removal. 2) A single questionnaire. OUTCOMES: 1) Primary: symptom reduction at 12 months after removal. Secondary: QOL (SF36) and satisfaction. SAMPLE SIZE/DATA-ANALYSIS: 1) Estimated 3000 women. 2) 600. 1) McNemar's test will be used to test changes in occurrence of symptoms after removal and paired T-test for change in QOL. 2) Analysis of covariance and Chi square to compare QOL and symptoms after various occlusion methods.

Doel van het onderzoek

1) Several symptoms will not improve after removal. 2) Symptoms are similar to other tubal occlusion methods

Onderzoeksopzet

• Inclusion phase prospective trial: cohort study 1; 3000 patients (expected to be 2.5 years) and cohort study 2 will be executed in parallel during the first year: Gynecologists, research nurses and researchers.

• Follow-up phase (12 months)

• Analytic phase (6 months) Analysis and report: researchers

Onderzoeksproduct en/of interventie

Participating women receive 4 questionnaires. The first will be send after their first visit followed by a second two months after the first visit to evaluate change in symptoms over time. The third and fourth form will be sent three and twelve months after the procedure. Ultrasound, X-ray and surgical findings will be registered before and during surgery. Women who decide to keep their Essure® will receive the questionnaires after their first visit, 3 and 12 months subsequently. The questionnaires contain a case report form (CRF) and QoL (using SF-36). The CRF will focus on complaints. Physicians will fill out 2 forms concerning pre- and perioperative data.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All women with Essure implants

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women who do not want to participate

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	3000
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	11-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6347
NTR-old	NTR6531
Ander register	METC : N16.081

Resultaten