CO2-Lasertonsillotomy versus tonsillectomy in adults; a randomized multicentre study

Gepubliceerd: 25-02-2018 Laatst bijgewerkt: 19-03-2025

Our hypothesis is that CO2 lasertonsillotomy under local anesthesia is followed by a significantly shorter recovery period, that it is an effective treatment for tonsil related complaints and that it has better secondary outcome results compared to...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29298

Bron
Nationaal Trial Register

Verkorte titel
TOMTOM-study

Aandoening

tonsillitis, tonsillolithiasis, halitosis, dysphagia, OSAS (tonsilrelated), chronisch/recidiverende tonsillitiden, tonsillolithiasis, halitosis, dysfagie, OSAS (tonsilgerelateerd)

Ondersteuning

Primaire sponsor: Hagaziekenhuis
LUMC
Viecuri
HMC
ZGT
RdG
MCL
JBZ

Gelderse Vallei
WZA
Amphia
Flevoziekenhuis
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of postoperative recovery days until resumption of daily activities.

Toelichting onderzoek

Achtergrond van het onderzoek

When conservative treatment fails in patients with tonsil related complaints, a tonsillectomy using the classical dissection technique can be performed.

In adults substantial morbidity following classical tonsillectomy under general anesthesia has been reported. An interesting alternative treatment for a specific selection of adult patients could be the CO2 lasertonsillotomy
under local anesthesia in an outpatient clinical setting.

Several articles describe good treatment results and a decrease in perioperative and postoperative morbidity.
Our hypothesis is that CO2 lasertonsillotomy under local anesthesia is followed by a significantly shorter recovery period, that it is an effective treatment for tonsil related complaints and that it has better secondary outcome results compared to classical tonsillotomy

Doel van het onderzoek

Our hypothesis is that CO2 lasertonsillotomy under local anesthesia is followed by a significantly shorter recovery period, that it is an effective treatment for tonsil related complaints and that it has better secondary outcome results compared to classical tonsillotomy.

Onderzoeksopzet

- pre-intervention

- 2 weeks post-intervention

- 6 weeks post-intervention

- 6 monts post-intervention

- 1 year post-intervention

- 2 year post-intervention

Onderzoeksproduct en/of interventie

- CO2-lasertonsillotomy under local anesthesia

- Cold dissection tonsillectomy

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- age ≥ 18 years

- tonsilrelated complaints with an indication for intervention
(chronic/rec. tonsillitis, tonsillolithiasis, halitosis, dysphagia, OSAS (tonsilrelated))

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- not cooperative / restless

- unable to open the mouth for a longer period

- history of peritonsillar abcess

- Friedman grade IV tonsils

- immunocompromised

- hemorrhagic diathesis / use of anticoagulants

- history of allergic reaction to local anesthetics

- in case of significant contra-indication for narcosis

- pregnancy

- extreme gag-reflex

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	25-01-2018
Aantal proefpersonen:	198
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	25-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50550
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6866
NTR-old	NTR7044
CCMO	NL57496.098.16
OMON	NL-OMON50550

Resultaten