

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

Gepubliceerd: 25-02-2018 Laatste 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...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Anders
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON29298

### Bron

NTR

### 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 months post-intervention
- 1 year post-intervention
- 2 year post-intervention

### **Onderzoeksproduct en/of interventie**

- CO2-lasertonsillotomy under local anesthesia
- Cold dissection tonsillectomy

## **Contactpersonen**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen**

## (Inclusiecriteria)

- age  $\geq$  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
Blinding:	Enkelblind
Controle:	Geneesmiddel

## 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