Xylitol/saline nasal irrigations in patients with CRS without polyps, a multicenter double-blind, randomized study in 66 subjects with CRS without polyps

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON50402

Source
ToetsingOnline

Brief title
Xylitol irrigations in CRS

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

Synonym
Chronic rhinosinusitis

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: KNO maatschap;ZWIK fonds

Intervention

Keyword: Chronic, Nasal-irrigation, RhinoSinusitis, Xylitol

Outcome measures

Primary outcome

Is there a significant difference in the VAS symptom score between saline only

nasal irrigations versus xylitol/saline irrigations?

Secondary outcome

is there a significant difference in the SNOT-22 score and objective nasal

endoscopic findings, between saline only nasal irrigations versus

xylitol/saline irrigations?

Study description

Background summary

Chronic Rhino Sinusitis (CRS) constitutes one of the commonest conditions encountered in medicine and affects nearly 14% of the population. CRS is a condition that can be difficult to treat and is associated with significant quality-of-life impairment1,2. Patients with CRS often complain of nasal blockage, nasal discharge, headaches or facial pain/ pressure and a reduction of smell. Symptoms must persist for a period of 12 weeks or longer in order to meet the criteria for CRS3. CRS can occur as chronic recurrent rhinosinusitis with symptom-free intervals in between, but is most of the time continuously present. Often there is a relationship with lower airway disease like asthma and allergy. In those cases, treatment of the nose often results in improvements of the concomitant asthma. Cornerstone of CRS treatment consists of topical nasal steroids combined with nasal saline irrigation. In case this treatment fails long term antibiotics might be added in selected patients and for some (multiple) surgical procedures (FESS) are needed3.

The CRS infection involves the formation of a bacterial biofilm that might play a significant role in the pathogenesis and persistence of CRS.
Xylitol is a five-carbon sugar alcohol that has gained relative prominence in the past decade as a naturally occurring antibacterial agent. It is generally not believed to possess its own antibacterial properties; rather it appears to enhance the body*s own innate bactericidal mechanisms In vitro, xylitol has a clear inhibitory effect on the formation of the experimental biofilms. Xylitol inhibits the acid production of cariogenic bacteria, but also prevents the formation of a multispecies biofilm Also, xylitol has been shown to reduce nasal bacterial carriage, otitis media, and dental caries in vivo

A pilot study conducted in 2011 by Weissman et al, showed that xylitol/saline irrigations resulted in greater improvement of symptoms of CRS as compared to saline only irrigation. Also, xylitol in water is a well-tolerated agent for sinonasal irrigation9.

Unfortunately, no more placebo controlled studies could be identified addressing the beneficial effect of xylitol in nasal saline irrigation for patients with CRS.

Study objective

In this study we will compare the therapeutic value of saline only versus xylitol/saline nasal irrigations in patients with CRS without nasal polyposis (CRSsNP). We will investigate several parameters by means of 2 different questionnaires and endoscopic findings.

Study design

This study will be a multicenter double-blind, randomized study in 66 subjects with CRSsNP, who have not previously underwent surgical procedures to the paranasal sinuses.

Subjects will be treated during 6weeks with saline only- or xylitol/saline irrigations three times daily and corticosteroid nose drops (Flixonase nasules ®) twice daily. Subjects will be randomized to use either saline only irrigations or xylitol/saline irrigations.

Signs and symptoms will be measured with disease specific questionnaires. Nasal endoscopy will give more objective information about the improvement status. Nasal culture is investigated using nasal swabs at the beginning of the study.

Intervention

nvt

Study burden and risks

The subject will fill in a SNOT 22 Questionnaire at week 1 and 6 on the computer. Also, the VAS score will be asked 2 times. The patient will rinse for 6 weeks, 3 times a day with Saline/Zoutxylitol solution. This rinsing is standard care.

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

1. Subjects must have a diagnosis of CRSsNP
2. Age * 18 and * 70 years.
3. Subjects must be willing to give Informed Consent and adhere to visit

schedules and medication restrictions.

Exclusion criteria

1. Previous surgical procedures to the paranasal sinuses
2. A clear dental origin of the sinus disease
3. Systemic or local antibiotic treatment less than 1 month before, or during the study.
4. Systemic steroid treatment less than 1 month before, or during the study.
5. Subjects administering homeopathica to nose or paranasal sinuses.
6. Nasal polyps.
7. Subjects in whom the infection can be explained by the following reasons:
a. Cystic fibrosis
b. Congenital mucociliary problems eg. Primary Ciliary Dyskinesia
8. Known systemic vasculitic and granulomatous disease.
9. AIDS or known to be HIV positive.
10. Smoking (in the past 6 months).
11. History of radiotherapy in head and neck region.
12. Severe anatomic abnormalities leading to an inability to administer the irrigation solution to one side of the nose (for example a severe septal deviation or a large bullous middle turbinate).
13. Craniofacial malformations.
14. Abnormalities requiring other modality of therapy (obstructive polyps, tumors, infection of dental origin).
15. Subject has a psychiatric, addictive, or any disorder that compromises ability to give truly Informed Consent for participation in this study.
16. Patient is currently enrolled in other investigational drug trial(s) or is receiving other investigational agent(s).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2017
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-05-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-09-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL59395.075.16