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Comparison of the new three dimensional “3D” with the conventional two dimensional “2D” endoscopic camera in surgery of the paranasal sinuses

Submission date
14/04/2018

Recruitment status
No longer recruiting

Registration date
26/04/2018

Overall study status
Completed

Last Edited
31/12/2020

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic rhinosinusitis is a common disease in which the cavities around the nasal passages become swollen. This may lead to a significant impairment of the quality of life in individuals suffering from the disorder. Medical therapy is the treatment of choice to reduce the symptoms. In severe disease, however, medical therapy may not be sufficient to control the disease activity and symptoms. In these cases, surgical therapy is indicated. The principle of surgical therapy is to open the narrow and blocked drainage pathways of the nasal sinuses and therefore to restore clearance of mucus and widen the access for medical treatment such as sprays. This procedure is known as “Functional Endoscopic Sinus Surgery” (FESS). Modern technology helps reduce the potential risks of FESS such as injury of the eye, the optic nerve, the important carotid artery and the brain which are neighbouring the paranasal sinuses. A key component of this endoscopic surgery of the paranasal sinuses is the long thin flexible tube, with a light source (endoscope) and camera which enables a good visualisation of the surgical area. The actual standard technique of endoscopic visualisation is using endoscopes combined with a high resolution camera, providing a 2-dimensional (2D) picture on a high resolution screen. A new development is recently commercially available providing a 3-dimensional picture, which gives additional information of “depth” in the surgical field. The visualisation of a 3-dimensional surgical field has the potential advantage to provide the surgeon with more realistic information about the anatomy of the surgical field which may be beneficial for surgical control and even reducing complications.
This study aims to compare the standard 2D-endoscopic surgical technique with the new commercially available 3D-endoscopic technique.

Who can participate?
Adult aged 18 years or above with chronic rhinosinusitis

What does the study involve?
As participant of the study, a standard sinus surgery procedure is performed, as indicated for the

treatment of the chronic rhinosinusitis, one side with the 2D endoscope, the other with the 3D endoscope. The time taken for each side is measured, as well as the subjective impression of the surgeon using the endoscopes.

What are the possible benefits and risks of participating?
There are no additional risks or benefits for the participants involved in this study
Where is the study run from?
1. ORL-Zentrum Klinik Hirslanden (Switzerland)
2. HNO-Universitätsklinik Ulm (Germany)
3. HNO-Klinik München Bogenhausen (Germany)
4. HNO-Universitätsklinik Graz (Austria)

When is the study starting and how long is it expected to run for?
January 2018 to December 2018

Who is funding the study?
ORL-Zentrum Klinik Hirslanden (Switzerland)

Who is the main contact?
Dr Hans Rudolf Briner (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Hans Rudolf Briner

Contact details
ORL-Zentrum Klinik Hirslanden
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Additional identifiers

Protocol serial number
BASEC Nr 2018-0005

Study information

Scientific Title
Comparison of 3D Endoscopy with 2D Endoscopy during functional endoscopic sinus surgery

Study objectives
This study aims to compare the standard 2D-endoscopic surgical technique with the new commercially available 3D-endoscopic technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kantonale Ethikkommission Zürich Ch-8090 Zurich Switzerland, 05/04/2018, ref: 2018-00005

Study design
International multicentre prospective randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic rhinosinusitis

Interventions
A total of 80 patients with chronic rhinosinusitis are evaluated. A Functional endoscopic sinus surgery (FESS) procedure is performed. All participants receive the 2D-endoscopic technique on one side, and 3D-endioscopic technique on the other side. In the first of the 20 patients, the side which is operated by the 2D-endoscope is determined by hazard (Los). In the further patients, the side is alternated after each patient.
There are four individual rhinosurgeons at four centers operating and evaluating 20 patients each.
The centers are Graz (Prof. V. Tomazic), Austria, Munich (Prof. A. Leunig), Germany, Ulm (PD Dr. F. Sommer), Germany and Zurich (KD Dr. H.R. Briner), Switzerland.
There is only the measurement of time of the procedure using the 2D and the 3D camera on each side during the procedure which is performed. Additionally, a questionnaire is filled by the surgeon asking for subjective impressions using the 2D or 3D camera. This questionnaire is designed for this study in order to look for subjective differences of the camera techniques.
There is no follow up for the study after the procedure.

Intervention Type
Device

Primary outcome(s)
Time of procedure is measured for 2D and 3D techniques during FESS procedure

Key secondary outcome(s))
The impressions of the surgeon on both 2D and 3D techniques are measured using a structured surgeon’s questionnaire at the end of the procedure.

Completion date
31/01/2020

Eligibility

Key inclusion criteria

1. Adult aged 18 years or above
2. Chronic rhinosinusitis
3. Candidate for endoscopic sinus surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Age below 18 years
2. Previous sinus operations
3. Unilateral or asymmetric disease
4. Severe comorbidities such as bleeding disorders
5. Inability or unwillingness to give consent for the study

Date of first enrolment
15/02/2019

Date of final enrolment
11/12/2019

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
ORL-Zentrum Klinik Hirslanden
Witellikerstrasse 40

Zurich
Switzerland
Ch-8032

Study participating centre
HNO-Universitätsklinik Ulm
Frauensteige 12
Ulm
Germany
89075

Study participating centre
HNO-Klinik München Bogenhausen
Dr. Gaertner GmbH
Possartstrasse 27-31
München
Germany
8169

Study participating centre
HNO-Universitätsklinik Graz
Auenbruggerplatz 1
Graz
Austria
8036

Sponsor information

Organisation
ORL-Zentrum Klinik Hirslanden

ROR
https://ror.org/014c2qb55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ORL-Zentrum Klinik Hirslanden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/12/2020	31/12/2020	Yes	No
Participant information sheet		23/04/2018	01/04/2019	No	Yes
Protocol file		23/04/2018	01/04/2019	No	No