Topical haemostatic agent Arista* AH compared to nasal packing following turbinate surgery: a prospective randomised controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51310

Source
ToetsingOnline

Brief title
Topical haemostatic agent Arista* AH after turbinate surgery

Condition

- Head and neck therapeutic procedures

Synonym
nasal turbinate reduction, Turbinate surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden

Source(s) of monetary or material Support: Onderzoeksbeurs Medisch Specialistisch Bedrijf Vrijgevestigd Collectief Leeuwarden (MSB VCL)

Intervention

Keyword: ARTUS

Outcome measures

Primary outcome

The aim of this study is to measure the amount of patient discomfort following turbinate surgery in the intervention group, treated with Arista* AH, compared to the control group, treated with non-absorbable Merocel® nasal packing. This will be measured by means of the Nasal Obstruction Symptom Evaluation (NOSE) scale and four questions on a Visual Analogue Scale (VAS).

Secondary outcome

The secondary aim of this study is to investigate the effects of Arista* AH on preventing excessive postoperative nasal bleeding, by calculating the percentage of excessive postoperative bleedings in the intervention group treated with Arista* AH versus the control group treated with non-absorbable Merocel® nasal packing.

Study description

Background summary

Postoperative nasal packing is common practise following turbinate surgery to prevent excessive postoperative nasal bleeding. However, nasal packing often has serious disadvantageous effects and causes patient discomfort, like nasal obstruction, pressure in the head and/or headache, dyspnoea, disturbed sleep and pain when removing the packing. Furthermore, the packing could cause infections and mucosal lesions upon removal. The aim of this study is to investigate the effects of the topical haemostatic device Arista* Absorbable

Haemostat (AH) on postoperative (dis)comfort and prevention of excessive postoperative bleeding. The use of this haemostatic device could improve regular patient care and decrease postoperative patient discomfort in the future.

Study objective

The main objective of this randomised controlled study is to investigate whether patients treated with Arista* AH have less postoperative complaints after inferior turbinate surgery compared to patients treated with non-absorbable Merocel® nasal packing. The secondary objective is to investigate the effects of Arista* AH on preventing excessive postoperative nasal bleeding after inferior turbinate surgery compared to nasal packing.

Study design

An open, prospective, randomised controlled trial with two arms: the control group with standard treatment of non-absorbable Merocel® nasal packing will be compared to the intervention group, which will receive Arista* AH after bilateral surgical reduction of the inferior turbinates.

Intervention

At the end of the procedure for turbinate surgery, the control group will receive the standard treatment of non-absorbable Merocel® nasal packing, whereas the intervention group will be treated with Arista* AH.

Study burden and risks

Turbinate surgery is carried out following normal protocol for both the intervention and control group. Patients who will be randomised into the control group will be treated with non-absorbable Merocel® nasal packing and will follow the normal protocol for postoperative management. Patients in the intervention group will be treated with Arista* AH at the end of surgery, which will not influence the duration of surgery. The intervention group will also follow the standard postoperative protocol, without the need for removing any nasal packing. Since Arista* AH is CE-marked and used within its intended purpose, the expected risks are regarded as minimal. Theoretically, there might be a slightly higher risk for a postoperative bleeding compared to the standard treatment, however, this has not been shown in practice according to a pilot study with ten patients treated with Arista* AH without any postoperative bleeding.
The burden for both the intervention and control group is to complete questionnaires at four different time points: just before surgery, three hours after surgery, the day after surgery upon waking up, and one week after surgery. Participation will not result in extra hospital visits.

Since the hypothesis is that the use of Arista* AH will result in less postoperative complaints, there could be a benefit is terms of reduced postoperative discomfort in the intervention group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adult patients aged >= 16 years
2. Scheduled for bilateral inferior turbinate surgery, with or without nasal septal surgery
3. Written informed consent

Exclusion criteria

1. Turbinate surgery combined with rhinoplasty and/or endoscopic sinus surgery
2. Nasal polyps
3. Use of anticoagulants
4. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2023
Enrollment:	118
Type:	Actual

Medical products/devices used

Generic name:	Arista AH;i.c.w. FlexiTip Applicator (class IIa)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-12-2022
Application type:	First submission

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL82005.099.22