A validation study on clinical symptoms and biomarkers in patients undergoing m3 extraction

Published: 05-03-2014
Last updated: 24-04-2024

Primary Objective: To investigate the clinical symptoms including pain response after third molar (i.e. wisdom teeth, or short: M3) extraction in relation to biomarkers and preoperative pain profile of individual subjects Secondary Objective: To...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Head and neck therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON40294

Source
ToetsingOnline

Brief title
Extraction Pain Biomarkers

Condition

- Head and neck therapeutic procedures

Synonym
Pain, Postextraction Pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, Extraction, Pain, Wisdomteeth

Outcome measures

Primary outcome

Interpatient pain response on NRS, biomarkers and genetic profile.

Secondary outcome

n.a.

Study description

Background summary

Postoperative pain response after surgical extraction of (wisdom) teeth may vary among patients. In identical surgical procedures, it has been observed that patient responses and severity of symptoms vary. Some have no postoperative pain, others have severe pain. Little is know to explain these variety in responses.

Study objective

Primary Objective: To investigate the clinical symptoms including pain response after third molar (i.e. wisdom teeth, or short: M3) extraction in relation to biomarkers and preoperative pain profile of individual subjects
Secondary Objective: To investigate the genetic profile of subjects with postoperative pain undergoing M3 extraction (exploratory purposes only)

Study design

This exploratory study will be performed in patients already scheduled for M3 extraction at the Department of Oral Maxillofacial Surgery of the University Medical Centre Groningen (UMCG). After the patients have given their consent to the study they will be interviewed, including pain rating with the Numeric Rating Scale (0-10). The scheduled extraction is executed and a drain is placed in the extraction cavities for collection of post-operative wound fluid and a blood sample to be used for genetic testing. Post-operative questionnaire taking, including NRS pain rating and wound fluid sampling will take place directly after M3 extraction, 30 min, 1h and 2 h post-extraction. Blood samples are taken direct after the extraction and two hours post-extraction. After the

last questionnaire, the drain is removed. The patients are asked to fill in a dairy for a period of 4 days at home that includes a questionnaire, NRS pain rating and medication taken. After 1 week the patient returns for follow-up interview and returns the dairy.

Study burden and risks

• Postsurgery waiting time of 2 hours
• Wound catheter in situ during 2 hours
• Filling in questionnaires and diary during four days
• One extra visit to the department of Oral Surgery
• Four wound fluid samples and two blood samples
• Neglible risks and minimal burden

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

Healthy subjects with age between 18 and 45 and BMI between 20 and 27 kg/m2 at screening

Exclusion criteria

Clinically significant acute illness within 7 days prior to study procedure.
Anti blood clotting medication
Donation of 1 or more units (approximately 450 mL) of blood or acute loss of an equivalent amount of blood within 90 days prior to study procedure.
Has received an experimental drug or used an experimental medical device within 30 days before the planned start of treatment.
Allergy to standard rescue medication Ibuprofen.
History of gastro-intestinal disturbances (gastropathy)
Psychological and/or emotional problems, which would render the informed consent invalid, or limit the ability of the subject to comply with the study requirements.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Surgical Drain
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43419.042.13