A, randomised, double-Blind, placebo-controlled pilot study with ibuprofen to implement the Post Surgical Dental Pain Model at the Kendle Clinical Pharmacology Unit in cooperation with Departments of Oral and Maxillofacial Surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31322

Source
ToetsingOnline

Brief title
Nvt

Condition

- Other condition

Synonym
dental pain

Health condition

tandpijn

Research involving
Human

Sponsors and support

Primary sponsor: Kendle International
Source(s) of monetary or material Support: zoals is opgegeven bij B6

Intervention

Keyword: 3rd molar extraction, ibuprofen, placebo, Post Surgical Dental Pain Model

Outcome measures

Primary outcome

To implement the Post Surgical Dental Pain Model at the Kendle Clinical

Pharmacology Unit in cooperation with Departments of Oral and Maxillofacial

Surgery

Secondary outcome

To show the ability to discriminate between the analgesic effect of a single

oral dose of Ibuprofen 400 mg and a single oral dose of placebo in patients

with moderate to severe pain following 3rd molar extraction.

Study description

Background summary

A, randomized, double-blind, placebo-controlled pilot study with ibuprofen to implement the Post Surgical Dental Pain Model at the Kendle Clinical Pharmacology Unit in cooperation with Departments of Oral and Maxillofacial Surgery

Study objective

Ibuprofen is a registered drug and belongs to the group of non-steroid inflammation inhibiting drugs. Those drugs inhibit inflammation, are sedative and fever reducing.
Ibuprofen is used in pain after dental or mouth chirurgy and after other operations, in rheuma, artrose, other affections in the joints, muscles or tendons that is attended with inflammation symptoms, dental pain, muscle pain, menstruation pain, headache, fever and pain after vaccination.

Study design

In total, a maximum of 20 healty male and female volunteers will participate in this study. The study includes a medical screening, a minimum of one 3rd molar extraction, a visit right after the extraction.

Study burden and risks

This study exists of one admission day. During admission the different questionnaires and assessments will be performed to judje the intensity of pain and the pain relief

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 be male or female and at least 18 years of age;
2. Females should not be pregnant;
3. Subjects must voluntarily sign a written informed consent agreement approved by the Independent Ethics Committee (IEC) after explanation of the nature and objectives of the study and prior to any study specific procedure;
4. Subject has had surgical extraction from up to four 3rd molars of which at least one is a fully or partially impacted mandibular 3rd molar;
5. Subject has a baseline measurement of at least moderate pain on a 4 point Likert scale (*none*, *slight*, *moderate*, *severe pain*) and a minimum of 50 mm on a 100 mm VAS Pain Intensity Scale (*no pain* - *very severe pain*);
6. The subject receives the study medication within 4 hours after completion of surgery;
7. Subjects must otherwise be in good health, based upon the results of medical history;
8. Subject is awake and alert and able to complete protocol-specified assessments.

Exclusion criteria

1. Female subjects that are pregnant (as shown by a positive urine pregnancy test) or lactating;
2. Subject should not have other (c honic) pain than pain caused by the molar extraction;
3. Subjects with contraindication for Ibuprofen like asthma, gastrointestinal bleeding, use of anticoagulants, bleeding disorders;
4. Subjects with contraindication for dental surgery;
5. Smoking is not allowed from pre-treatment until discharge;
6. Treatment with short-acting analgesics (paracetamol, aspirin) within 6 hours prior to surgery, ibuprofen within 10 hours prior to surgery and/or long-acting NSAIDs (naproxen, etc) or COX-2 inhibitors within 48 hours prior to surgery. Except for preoperative en intraoperative anaesthetic, treatment with drugs that can confound the analgesic response (like tricyclic antidepressants, sedatives, tranquilizers, antihistamines) within 5 half lifes of the respective drug prior to surgery;
7. Subjects who receive surgical medication other than lignocain 2% (with epinep hine 1:100,000?); to be discussed

8. Subjects with a presence or a history of clinically relevant conditions in the gastrointestinal, hepatic, renal, urogenital, cardiovascular, metabolic, endocrine or central and peripheral nervous systems;
9. Subjects with active presence or history of alcoholism or drug addiction;
10. Subjects with positive alcohol and drugs screen;
11. Subjects with a relevant food or drug hypersensitivity or allergy;
12. Subject with intolerance to any ingredients of the placebo;
13. Subjects who are considered unsuitable to participate in the study for any reason in the opinion of the principal investigator;

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	Ibuprofen 400
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-03-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-03-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-05-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-05-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2007-001175-11-NL
CCMO	NL16872.040.07