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Loxoprofen versus diclofenac potassium in post-dental extraction pain relief and side effects

Submission date
04/11/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Tooth extraction remains one of the common procedures in developing countries. However, one of a common postoperative complication of extraction is severe pain, so it is important to prescribe some analgesic to relief that pain. The aim of this study is to compare between two commonly prescribed oral analgesics in our country (Saudi Arabia) for reducing pain after tooth extraction with the least side effects (Roxonin , Rabidus).

Who can participate?
Participants over the age of 18, undergoing tooth extraction at the study site

What does the study involve?
Pain assessment was carried out postoperatively by 6 hours and every 12 hours for 3 days using visual analogue scale

What are the possible benefits and risks of participating?
Benefits: reducing post-extraction pain by receiving free analgesics.
Risks: There are no direct risks. If there is an allergy to the treatment the participant will be stopped immediately.

Where is the study run from?
Taibah University College of Dentistry, Saudi Arabia

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TUCDREC/20180102/Alaufi

Study information

Scientific Title
Roxonin versus Rabidus in post-dental extraction pain relief and side effects: a randomized, triple-blind, controlled clinical trial

Study objectives
There will be no difference between Rabidus and Rexonin oral analgesics for controlling post-dental extraction pain and side effects (e.g. vomiting).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/02/2019, Taibah University College of Dentistry Research Ethics Committee (Prince Naif Road, Almadinah, 42353, Saudi Arabia; amramadan@taibahu.edu.sa), ref: TUCDREC /20180102/Alaufi

Study design

Interventional single-centre triple-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pain after tooth extraction

Interventions
Eligible patients after tooth extraction were randomized to the study interventional groups (Rapidus or Roxonin) by means of drawing lots and intervention and control were coded as A or B. The codes of the drugs were kept by an independent monitor and were unveiled until all data underwent analyses. The researcher, the clinicians, and patients were blinded to the codes of the drugs A and B during the course of the study. When the participant opens the envelope, he /she found the instruction of how to take the medicine as the manufacture instructed.

Medicine was taken for three days and pain assessed by VAS after 6 hours and then every 12 hours for three days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Roxonin (Loxoprofen) Rabidus (Diclofenac Potassium)

Primary outcome measure
Pain after tooth extraction by using VAS (visual analogue scale) , the timepoint was after 6 hours of tooth extraction and every 12 hours for three days.

Secondary outcome measures
Side effects over the trial period (three days)

Overall study start date
01/01/2018

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Age 18-70 years old .
2. Literate people (speaking, reading and writing Arabic or English).
3. Healthy or with controlled systemic disease as recommended by the American Society of Anesthesiologists and had no risk from the administration of LA with adrenaline (hyperthyroidism).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Could not give informed consent (e.g. mental disorder)
2. Teeth with reversible pulpitis
3. History of taking anticoagulant, active peptic ulcer and attack of asthma

Date of first enrolment
20/01/2018

Date of final enrolment
24/03/2018

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Taibah University College of Dentistry
Prince Naif Road
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Sponsor information

Organisation
Taibah University College of Dentistry

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Sponsor type
Government

Website
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ROR
https://ror.org/01xv1nn60

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
20/12/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/12/2019	03/01/2023	Yes	No