







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

Submission date 04/11/2019	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol not yet added
Registration date 05/11/2019	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 03/01/2023	Condition category Oral Health	 Raw data not yet added
		 Study completed

Plain English Summary

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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Protocol/serial number

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 hypothesis

There will be no difference between Rabidus and Raxonin 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

Condition

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

Overall study end date

01/03/2018

Eligibility

Participant 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

Participant 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

Recruitment start date

20/01/2018

Recruitment end date

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

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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