# Loxoprofen versus diclofenac potassium in postdental extraction pain relief and side effects

<b>Submission date</b> 04/11/2019	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
<b>Registration date</b> 05/11/2019	Overall study status Completed	<ul><li>Statistical analysis plan</li><li>[X] Results</li></ul>
<b>Last Edited</b> 03/01/2023	<b>Condition category</b> Oral Health	[] 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? Dr Majd Almutairi m.rja\_almutairi@hotmail.com

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Majd Almutairi

#### Contact details

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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 Almadinah Saudi Arabia 42353

# Sponsor information

# Organisation

Taibah University College of Dentistry

#### Sponsor details

Prince Naif road Almadinah Saudi Arabia 42353 +966 14-8618888 information@taibahudental.com

#### Sponsor type

Government

#### Website

https://www.taibahu.edu.sa

#### **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