Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of platelet-rich plasma (PRP) on dental extraction in patients at risk of medication related osteonecrosis of the jaw

Protocol summary

Study aim
The aim of this study was to assess the efficiency, as clinical healing, of the application of platelet-rich plasma (PRP) gel in the extraction sockets in patients treated with bisphosphonates at risk of medication-related osteonecrosis of the jaw (MRONJ)

Design
single center, single-arm not randomized clinical trial

Settings and conduct
1) Clinical Evaluation 2) Computer Tomography (CT) evaluation if needed; oral hygiene instructions; pre-operatory medical therapy prescription; PRP preparation 3) Surgical procedure 4) Suture removal 5) Follow-up visits at 15, 30, 90, 180, 360 days

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) age > 18 years 2) metabolic bone disease and/or malignant tumors 3) treatment with bisphosphonates because of the underlying disease 4) required tooth extraction Exclusion criteria: 1) signs of MRONJ in the surgical area 2) previous history of irradiation to the head and neck area 3) neoplastic involvement of the jaws 4) poor general conditions 5) pregnant or breast-feeding women

Intervention groups
The surgical protocol expected: 1)Chlorhexidine 0,2% mouthwashes 30 ml swished up to 60 seconds 2) local anesthesia achieved using 3% mepivacaine hydrochloride without adrenaline 3) elevation of a full-thickness mucoperiosteal flap 4) tooth luxation and avulsion 5) if necessary, osteoplasty 6) debridement of the post-extraction socket and irrigation with rifamycin sodium 7) application of a single dosage of autologous PRP (Plateltex ACT System ®, Biomed, Modena, IT) 8) suture. To prepare the PRP and to induce its gelation, the materials provided by the manufacturer were used and the provided instructions followed [Mazzucco L, Balbo V, Cattana E, Borzini P. Platelet-rich plasma and platelet gel preparation using Plateltex. Vox Sang. 2008 Apr;94(3):202-8.]

Main outcome variables
Absence of signs related to MRONJ (Healing)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180329039159N2**
Registration date: **2019-08-05, 1398/05/14**
Registration timing: **retrospective**

Last update: **2019-08-05, 1398/05/14**
Update count: **0**

Registration date
2019-08-05, 1398/05/14

Registrant information

Name
Rodolfo Mauceri

Name of organization / entity
University of Palermo

Country
Italy

Phone
+39 091 655 2221

Email address
rodolfo.mauceri@unipa.it

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-06-10, 1394/03/20

Expected recruitment end date
2016-06-30, 1395/04/10

Actual recruitment start date
2015-06-10, 1394/03/20

Actual recruitment end date

2016-04-30, 1395/02/11

Trial completion date

2016-04-30, 1395/02/11

Scientific title

Effect of platelet-rich plasma (PRP) on dental extraction in patients at risk of medication related osteonecrosis of the jaw

Public title

Effect of PRP to prevent MRONJ after dental extraction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

metabolic bone disease and/or malignant tumors treatment with bisphosphonates because of the underlying disease required tooth extraction

Exclusion criteria:

clinical or radiological signs of medication related osteonecrosis of the jaw in the surgical area previous history of irradiation to the head and neck area neoplastic involvement of the jaws poor general conditions pregnant or breast-feeding women

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Palermo Ethics Committee 1

Street address

129 Via del Vespro

City

Palermo

Postal code

90127

Approval date

2015-06-10, 1394/03/20

Ethics committee reference number

6 - 2015

Health conditions studied

1

Description of health condition studied

medication related osteonecrosis of the jaw

ICD-10 code

m87.1

ICD-10 code description

Osteonecrosis due to drugs

Primary outcomes

1

Description

Absence of signs related to MRONJ (Healing)

Timepoint

We scheduled follow-up visits to remove the suture seven days after surgery, and visited patients on the fifteenth day, and continued on month one, three, six and twelve

Method of measurement

Clinical and radiological signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group; the surgical protocol expected: 1) Chlorhexidine 0,2% mouthwashes 30 ml swished up to 60 seconds; 2) local anesthesia achieved using 3% mepivacaine hydrochloride without adrenaline; 3) elevation of a full-thickness mucoperiosteal flap; 4) tooth luxation and avulsion were gently performed with elevators and forceps; 5) if necessary, osteoplasty 6) debridement of the post-extraction socket with miller surgical curette and irrigation of the sockets with rifamycin sodium; 7) application of a single dosage of autologous platelet-rich plasma (Plateltex ACT System ®, Biomed, Modena, IT) ; 8) tension-free soft tissue closure. To prepare the PRP and to induce its gelation, the materials provided by the manufacturer were used and the provided instructions followed [Mazzucco L, Balbo V, Cattana E, Borzini P. Platelet-rich plasma and plateletgel preparation using Plateltex. Vox Sang. 2008 Apr;94(3):202-8.]

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Surgical, Oncological and Oral Sciences, University of Palermo

Full name of responsible person
Prof. Giuseppina Campisi

Street address
129 Via del Vespro

City
Palermo

Postal code
90127

Phone
+39 091 655 2221

Email
campisi@odonto.unipa.it

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Palermo

Full name of responsible person
Prof. Giusepina Campisi

Street address
129 Via del Vespro

City
Palermo

Postal code
90127

Phone
+39 091 655 2221

Email
campisi@odonto.unipa.it

Grant name
not applicable

Grant code / Reference number
not applicable

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
University of Palermo

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Palermo

Full name of responsible person
Giuseppina Campisi

Position
Full Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
129 Via del Vespro

City
Palermo

Province
Sicily

Postal code
90127

Phone
+39 091 655 2236

Email
campisi@odonto.unipa.it

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Palermo

Full name of responsible person
Rodolfo Mauceri

Position
Tutor

Latest degree
Ph.D.

Other areas of specialty/work
Dentistry

Street address
7 Via Benedetto Civiletti

City
Palermo

Province
Palermo

Postal code
90141

Phone
+39 091 655 2221

Email
rodolfo.mauceri@unipa.it

Person responsible for updating data

Contact

Name of organization / entity
University of Palermo

Full name of responsible person
Giuseppina Campisi

Position
Full Professor

Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
129 Via del Vespro
City
Palermo
Province
Palermo
Postal code
90127
Phone
+39 091 655 2236
Email
campisi@odonto.unipa.it

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available