

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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-operative 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

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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**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

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## 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

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Full Professor

**Latest degree**

Specialist

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**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