

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Conservative surgical treatment of bisphosphonate-related osteonecrosis of the jaw with Er,Cr:YSGG laser and platelet-rich plasma in cancer patients

#### Protocol summary

##### Study aim

This study aimed to evaluate the effect on clinical healing of a combined treatment consisting of laser-assisted surgery and Platelet rich plasma (PRP) in cancer patients affected by bisphosphonates related osteonecrosis of the jaw (BRONJ)

##### Design

Cancer patients affected by BRONJ, single arm, not randomized

##### Settings and conduct

1) Clinical Evaluation; 2) Computer Tomography (CT) evaluation; lesions' classification following SIPMO-SICMF staging system; scaling (when required) and oral hygiene instructions; pre-operative medical therapy prescription; Platelet rich-plasma (PRP) preparation; 3) Surgical procedure: Er,Cr:YSGG Laser surgery, PRP application, Flap suture; 4) Suture removal and clinical control; 5) Follow-up visits at 15 days, one month, three, six, twelve months;

##### Participants/Inclusion and exclusion criteria

Patients were eligible for the study if they had: 1) age  $\geq$  18 years; 2) cancer; 3) treatment with bisphosphonates (BPs) because of the underlying cancer. Patients were excluded from the study if they had: 1) previous history of irradiation to the maxillofacial area; 2) neoplastic involvement of the jaws; 3) previous surgical treatment to the jaws; 4) poor general conditions.

##### Intervention groups

The surgical protocol consisted of: 1) elevation of a full-thickness mucoperiosteal flap to expose the surgical area; 2) bony curettage (debridement) and sequestrectomy of the necrotic bone, whether required, using a Er,Cr:YSGG laser; 3) application of autologous PRP; 4) tension-free soft tissue closure

##### Main outcome variables

We defined successful treatment the absence of clinical and radiological signs of BRONJ relapse (healing) or, in

turn, the transition from a higher stage to a lower one (improvement).

#### General information

##### Reason for update

##### Acronym

ErPRP

##### IRCT registration information

IRCT registration number: **IRCT20180329039159N1**

Registration date: **2018-06-12, 1397/03/22**

Registration timing: **retrospective**

Last update: **2018-06-12, 1397/03/22**

Update count: **0**

##### Registration date

2018-06-12, 1397/03/22

##### 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

2014-01-01, 1392/10/11

##### Expected recruitment end date

2015-12-31, 1394/10/10

##### Actual recruitment start date

2015-06-10, 1394/03/20  
**Actual recruitment end date**  
2015-11-02, 1394/08/11  
**Trial completion date**  
empty

**Scientific title**

Conservative surgical treatment of bisphosphonate-related osteonecrosis of the jaw with Er,Cr:YSGG laser and platelet-rich plasma in cancer patients

**Public title**

Er,Cr:YSGG laser and platelet-rich plasma in treatment of ONJ

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

age ≥ 18 years cancer; treatment with BPs because of the underlying cancer

**Exclusion criteria:**

previous history of irradiation to the maxillofacial area  
neoplastic involvement of the jaws  
previous surgical treatment to the jaws  
poor general conditions

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

Actual sample size reached: **10**

**Randomization (investigator's opinion)**

Not randomized

**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**

Comitato Etico Palermo 1

**Street address**

Via del Vespro 129

**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**

Bisphosphonates related osteonecrosis of the jaw

**ICD-10 code**

M87.1

**ICD-10 code description**

Osteonecrosis due to drugs

**Primary outcomes**

1

**Description**

Absence of clinical and radiological signs of BRONJ relapse (healing) or, in turn, the transition from a higher stage to a lower one (improvement).

**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 consisted of: 1) elevation of a full-thickness mucoperiosteal flap to expose the surgical area; 3) bony curettage (debridement) and sequestrectomy of the necrotic bone, whether required, using a Er,Cr:YSGG laser; 4) application of autologous platelet rich plasma (PRP); 5) tension-free soft tissue closure

**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**

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**Other areas of specialty/work**

Dentistry

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

None

**Full name of responsible person**

None

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**Email**

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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**

None

**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

**Person responsible for scientific 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**

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**Person responsible for updating data****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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## 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**

Not applicable

**Informed Consent Form**

No - There is not 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