Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-operatory 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 ≥ 18 years; 2) cancer; 3) treatment with bisphosphnates (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; 3) bony curettage (debridement) and sequestrectomy of the necrotic bone, whether required, using a Er,Cr:YSGG laser; 4) application of autologous PRP; 5) 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
None
Full name of responsible person
None
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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

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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