

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The role of antibiotic prophylaxis in reducing bacterial contamination of autologous bone graft collected from implant site

Protocol summary

Summary

Background: In the presence of small bone defects, the bone particles produced during the preparation of the dental implant site could be used to cover the exposed implant surface. The oral cavity is not sterile and a large number of experimental studies are available on the bacterial flora inhabiting the healthy oral cavity. Bacterial contamination of the bone debris may be a cause of failure of osseointegrated oral implants. A number of studies have suggested different methods to reduce bacterial contamination of the collected bone, including antibiotic prophylaxis. Nevertheless, the role of antibiotic prophylaxis to reduce bacterial contamination of bone particles is still controversial. Aim: To evaluate if antibiotic prophylaxis reduces the physiologically occurring bacterial contamination of bone particles collected directly from the burs used for implant site preparation Design: Interventional, single-centre and double blinded study. Thirty patients are randomly allocated to the Test and Control groups. Antibiotic prophylaxis is given to the Test patients. The Control patients do not take antibiotic prophylaxis at all. All patients will undergo the same surgical procedure (ie, implant site preparation). Major inclusion criteria: Good general and oral health, need to replace the absence of one tooth with an implant supported prosthesis. Major exclusion criteria: Medical contraindications to implant therapy, active caries and chronic/aggressive periodontitis. Intervention: One 1 gr. tablet of amoxicillin + clavulanic acid is given 12 hours and 1 hour before the surgery. Main outcome measures: Reduction of bacterial contamination of bone particles collected directly from the burs.

General information

Acronym

*

IRCT registration information

IRCT registration number: **IRCT2017102537002N1**

Registration date: **2017-11-14, 1396/08/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-14, 1396/08/23

Registrant information

Name

Giuseppe Pizzo

Name of organization / entity

University of Palermo

Country

Italy

Phone

39-091-6552221

Email address

giuseppe.pizzo@unipa.it

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2015-02-28, 1393/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of antibiotic prophylaxis in reducing bacterial contamination of autologous bone graft collected from implant site

Public title

Evaluating a protocol of antibiotic prophylaxis to reduce bacterial contamination of the bone particles collected directly from the burs used for preparation of the dental implant site

Purpose

Prevention

Inclusion/Exclusion criteria

The study is conducted in healthy human volunteers. Inclusion criteria: a need to replace the absence of one tooth with an implant supported prosthesis, no systemic diseases or contraindications to surgical procedures, no pregnancy, no routine drug use, no history of antibiotic therapy for 6 months prior to the study, no allergy to penicillin or related drugs, absence of carious lesions and local active inflammatory conditions or chronic/aggressive periodontitis, presence of alveolar ridges of class II or III of Cawood and Howell (1988). Exclusion criteria: systemic diseases that affect jaws and periodontium; orthodontic appliance; active dental caries; chronic diseases of the oral mucosa; chronic antibiotic usage; antiplaque mouthrinse consumption; drugs consumption which affect saliva flow rate; radiotherapy history.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Although the patients are randomly allocated to the Test and Control groups, the study does not aim to evaluate any effects on health outcomes. The physiologically occurring bacterial contamination of bone particles produced during the preparation of the implant site does not represent a "health outcome" sensu stricto. Moreover, only a minimal part of the study is conducted in a clinical setting (the collection of bone particles during the implant site preparation), while the core of the study is performed in a laboratory setting. The operator performing surgical procedures and collection of bone particles, the laboratory workers assessing the microbiological outcomes, and authors involved in organizing and managing the analysis of data will be blinded to group assignment.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Comitato Etico Palermo 1

Street address

A.O.U. Policlinico Paolo Giaccone, Via del Vespro 129

City

Palermo

Postal code

90127

Approval date

2014-07-21, 1393/04/30

Ethics committee reference number

8/2014

Health conditions studied**1****Description of health condition studied**

Bacterial contamination of autologous bone particles collected from dental implant site

ICD-10 code

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ICD-10 code description

*

Primary outcomes**1****Description**

Reduction of bacterial contamination

Timepoint

Following end of treatment (antibiotic prophylaxis), during implant site preparation

Method of measurement

Counts (CFU) and identification of isolated bacteria

Secondary outcomes

empty

Intervention groups**1****Description**

TEST Intervention: Antibiotic prophylaxis is prescribed to the Test group patients. One 1 gr. tablet of amoxicillin + clavulanic acid (Augmentin, GlaxoSmithKline, Verona, Italy) is given to the test group patients 12 hours and 1 hour before the surgery. All patients (Test and Control groups) will undergo the same surgical procedure (ie, implant site preparation). After local anesthesia, a full-

thickness flap is made and the implant site is prepared with calibrated drills at 600 revolutions per minute, irrigated by cooled saline solution. During each step of the calibrated drills, bone particles on the coils are collected and placed in a 15 ml sterile tube containing 10 ml of prereduced thioglycolate broth. The collected samples are sent to the microbiology laboratory within one hour.

Category

Treatment - Drugs

2

Description

CONTROL Intervention: The Control group patients do not take antibiotic prophylaxis at all (No intervention). All patients (Test and Control groups) will undergo the same surgical procedure (ie, implant site preparation). It is described in the "TEST intervention" field.

Category

Treatment - Drugs

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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Street address

Via del Vespro 129

City

Palermo

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

None

Full name of responsible person

N/A

Street address

N/A

City

N/A

Grant name

Grant code / Reference number

*

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Palermo

Full name of responsible person

Giuseppe Pizzo

Position

Associate Professor

Other areas of specialty/work

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*

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty