ISRCTN95407036 https://doi.org/10.1186/ISRCTN95407036

Influence of the suturing technique on the wound healing of the palate after obtaining a connective tissue graft

Submission date	Recruitment status	[_] Prospectively registered
22/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2018	Ear, Nose and Throat	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gingival recession (also known as receding gums) is when the roots of the teeth are exposed when the gum tissue it lost. One of the main treatments is a gum transplant, where gum tissue (called a graft) is collected from other parts of the mouth and placed on the areas where the gums have receded. There are many different surgical techniques used described to obtain a connective tissue graft from the palate in order to decrease patient discomfort, but there is no clear answer about the influence of the suture technique and the residual flap thickness on the early healing of the donor site. The aim of this study is to examine if wound healing is related to suturing, and if palatial thickness is related to postoperative pain.

Who can participate?
Adults aged 18 and older who have gingival recession.

What does the study involve?
All participants undergo a procedure where a connective tissue graft is taken from the palate using a single incision technique. Participants are randomly allocated to one of two groups. Those in the first group have the donor site sutured with one method. Those in the second group receive a criss-cross suture used. The same drug therapy is given to all patients. One week after surgery, at suture removal, the healing of the donor site is evaluated.

What are the possible benefits and risks of participating?
There are no direct benefits or risks taking part in the study.

Where is the study run from?
Universitat internacional de Catalunya (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to May 2017

Who is funding the study?
Universitat Internacional de Catalunya (Spain)

Who is the main contact?
Dr Giovanni Maino (Public)

Contact information

Type(s)
Public

Contact name
Dr Giovanni Maino

Contact details
Josep Trueta Street, s/n
Hospital Universitari General de Catalunya
Vicenza
Italy
08195

Type(s)
Scientific

Contact name
Dr Cristina Valles

Contact details
calle Josep tureta
Barcelona
Spain
08190

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PER-ECL-2015-03

Study information

Scientific Title
Influence of suturing technique and postoperative palatal flap thickness on wound healing and patient morbidity after connective tissue harvesting. A randomized controlled clinical trial

Study objectives
1. Wound healing is correlated to the suturing techniques
2. The post-operative palatal thickness is correlated with the early wound healing of the donor site
3. Palatal thickness is correlated with postoperative pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitè Etic d'Investigacio Clinica, 20/11/2015, ref: PER-ECL-2015-03

Study design
Single centre randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Palatal healing

Interventions
Using a computerized randomisation method, participants are allocated to one of two groups.

Group 1: Participants receive a continuous interlocking suture used in the donor site
Group 2: Participants receive a criss-cross suture used in the donor site.

The envelope indicating the group to which the patient belongs was opened at the time of the suture. Before the surgery measurement of the palate was taken with and endodontic file and flowable light curing composite. After the obtention of a standardized connective tissue graft (12mm x 8mm x 1,5mm) using the single incision technique, measurement of the residual flap thickness was taken with the same method explained before.

After one week, healing of the donor site is evaluated and pain perception recorded daily until 8 weeks after the intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure

Association between suture technique and early healing index is measured one week after surgery and after suture removal, the early-wound healing index (EHI) using five different degrees:
1. Complete flap closure without fibrin line at the palate
2. Complete flap closure with fibrin line at the palate
3. Complete flap closure with small fibrin clot(s) at the palate
4. Incomplete flap closure with partial necrosis of the palatal tissue
5. Incomplete flap closure with complete necrosis of the palatal tissue (more than 50 % of the former flap is involved)

Secondary outcome measures
1. Association between preoperative palatal thickness and early healing is measured one week after surgery using a early-wound healing index (EHI) (Fickl et al. 2014) and the preoperative measurement taken with the endodontic file and light curing flowable composite
2. Association between postoperative palatal flap thickness and early healing is measured one week after surgery using a early-wound healing index (EHI) (Fickl et al. 2014) and the postoperative measurement taken with the endodontic file and light curing flowable composite
3. Pain Perception of the patients was determined with VAS pain values daily until 8 weeks after surgery

Overall study start date
20/09/2015

Completion date
20/05/2017

Eligibility

Key inclusion criteria
1. Men and women over 18 years old
2. Showing Miller Class I,II or III (Miller 1985) single gingival recession

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients total, 20 each group

Key exclusion criteria
1. Any systemic conditions that might impact directly on the systemic inflammatory status (e.g. autoimmune diseases)

2. Severe cognitive or psychiatric disorders
3. Chronic immunosuppressant therapy
4. Lactating females and current pregnancy
5. Patients with coagulation disorders excluded from the trial
6. Smokers who consume more than 10 cigarettes per day
7. Patients using partial or full denture, which has any contact with the palate

Date of first enrolment
21/10/2015

Date of final enrolment
20/02/2017

Locations

Countries of recruitment
Spain

Study participating centre
Universitat Internacional de Catalunya
Calle Josep Tureta s/n
Barcelona
Spain
08190

Sponsor information

Organisation
Universitat Internacional de Catalunya

Sponsor details
Calle Josep Tureta
San Cugat del Valles
Spain
08195
+34 93 504 20 30
clinica@uic.es

Sponsor type
University/education

ROR
https://ror.org/00tse2b39

Funder(s)

Funder type
University/education

Funder Name
Universitat Internacional de Catalunya

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact reviewed journal

Intention to publish date
15/07/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date