ISRCTN12328428 https://doi.org/10.1186/ISRCTN12328428

Use of autologous blood products to enhance the survival of corneal transplants

Submission date
27/07/2023

Recruitment status
No longer recruiting

Registration date
28/07/2023

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In a corneal transplant all or part of a damaged cornea (the clear outer layer at the front of the eye) is removed and replaced with healthy cornea tissue from the eye of a dead donor. During corneal transplantation its normal for some corneal cells to be lost, which can lead to problems like the transplanted tissue not working properly or being rejected by the body. Inflammation and manipulation of the tissue are significant factors in causing the loss of these cells after surgery. In previous studies, using a substance called plasma rich in growth factors (PRGF), which is a product extracted from the patients' blood, can help protect the cells from this stress and prevent them from dying. The aim of this study is to see if soaking the corneal cells in PRGF for 15 minutes during surgery can reduce the number of cells lost after the procedure. The researchers will be assessing both how well it works and if it's safe to do.

Who can participate?
Patients over 18 years old undergoing corneal transplantation at Clinica Barraquer de America

What does the study involve?
Participants will be randomly allocated to receive corneal transplants incubated with either activated platelet-rich plasma (aPRP) or PRGF.

What are the possible benefits and risks of participating?
Benefits: Lower endothelial cell loss compared to usual corneal transplant procedures and longer transplant survival.
Risks: Same as any usual corneal transplant

Where is the study run from?
Instituto Barraquer de América (Colombia)

When is the study starting and how long is it expected to run for?
June 2019 to March 2023

Who is funding the study?
Francisco Barraquer-Coll Research Grant, Instituto Barraquer de América (Colombia)

Who is the main contact?
Carolina Mercado, cxm2533@med.miami.edu

Contact information

Type(s)
Principal Investigator

Contact name
Dr Carolina Mercado

ORCID ID
http://orcid.org/0000-0002-1608-3563

Contact details
900 nw 17th st
Miami
United States of America
33136
+57 (0)7868900892
cxm2533@med.miami.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
27921992

Study information

Scientific Title
Safety and efficacy of brief intraoperative incubation of full-thickness corneal grafts in autologous plasma products for reducing postoperative endothelial cell loss

Study objectives
Autologous plasma products (aPRP and PRGF) throughout its antioxidant role may prevent the cytotoxic effects induced by oxidative stress, thus reducing corneal endothelial cell loss after penetrating keratoplasty.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/06/2021, CEI-ESOIBA (Ac 100 #18a-51, Bogota, -, Colombia; +57 (0)6012187077; mojimenezp.esoiba@barraquer.edu.co), ref: N/A

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of corneal endothelial cell loss after penetrating keratoplasty

Interventions
Prospective randomized trial of patients undergoing penetrating keratoplasty by three surgeons. Participants who agreed to undergo intervention were randomly assigned by block randomisation to either of the treatment groups (aPRP incubation for 15 minutes intraoperatively or PRGF incubation for 15 minutes intraoperatively). Patients who declined intervention were followed as controls. The effect of aPRP on postoperative endothelial cell loss following corneal transplantation was evaluated by specular microscopy. The researchers also assessed pachymetry and intraocular pressure on follow-up.

Intervention Type
Supplement

Primary outcome measure
Postoperative endothelial cell loss using endothelial cell counts on specular microscopy at 1st, 3rd, and 6th postoperative months

Secondary outcome measures
1. Hexagonality measured using specular microscopy at 1st, 3rd, and 6th postoperative months
2. Corneal thickness using specular microscopy at 1st, 3rd, and 6th postoperative months

Overall study start date
04/06/2019

Completion date

07/03/2023

Eligibility

Key inclusion criteria
1. Patients older than 18 years
2. Undergoing penetrating keratoplasty for any reason by the previously mentioned surgeons from June 2021 to December 2022
3. All the tissue was provided by the same Eye Bank (COBANCOL), with no more than 14 days of preservation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Tissue from another institution operated by other surgeons
2. Patients from vulnerable populations.
3. Patients with renal failure, anemia, or immunosuppressed
4. Patients with previous trabeculectomies or glaucoma valve implants

Date of first enrolment
28/06/2021

Date of final enrolment
02/02/2023

Locations

Countries of recruitment
Colombia

Study participating centre

Clinica Barraquer de America
Ac 100 #18a-51
BOGOTA
Colombia
-

Sponsor information

Organisation
Instituto Barraquer de América

Sponsor details
Ac 100 #18a-51
Bogotá
Colombia
-
+57 (0)2187077
mojimenezp.esoiba@barraquer.edu.co

Sponsor type
Research organisation

Website
https://www.institutobarraquer.com/

ROR
https://ror.org/02q3wgj37

Funder(s)

Funder type
Research organisation

Funder Name
Francisco Barraquer-Coll Research Grant

Results and Publications

Publication and dissemination plan
The researchers have presented preliminary results of this study in: Eighth Fuchs Symposium, 59th annual Bascom Palmer Residents Day, EBAA Cornea and Eye Banking Forum 2022, ASCRS 2022.

Intention to publish date
30/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Carolina Mercado MD (caromercadoa@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/08/2024	17/04/2025	Yes	No