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

Submission date	Recruitment status	Prospectively registered	
21/01/2023	No longer recruiting	Protocol	
Registration date 28/07/2023	<b>Overall study status</b> Completed	Statistical analysis plan	
		[X] Results	
Last Edited 17/04/2025	<b>Condition category</b> Eye Diseases	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

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# 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

 Patients older than 18 years
Undergoing penetrating keratoplasty for any reason by the previously mentioned surgeons from June 2021 to December 2022
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?
<u>Results article</u>		12/08/2024	17/04/2025	Yes	No