

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Open-label, randomized study to evaluate efficacy and safety of Suprotac® in comparison with Prograf® in liver transplant patients in Iran

Protocol summary

Study aim

Investigation of the efficacy and safety of Suprotac® compared with Prograf® in liver transplant patients in Iran

Design

Randomized Clinical Trial; Two arms in parallel; Open-label; Phase 4 with 196 patients

Settings and conduct

Eligible patients are randomized into two groups of Suprotac® or Prograf®. Tacrolimus in both groups is administered at a dose of 0.1–0.15 mg/kg orally on the first day post-transplant. Then, dose will be adjusted if needed to reach the desired trough level.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18 to 70
Exclusion criteria: Receiving any investigational products within the last 30 days; contraindication for tacrolimus; Glomerular Filtration Rate greater than 30

Intervention groups

Group 1: Suprotac® (Nanoalvand) Group 2: Prograf® (Astellas) Tacrolimus in both groups is administered at a dose of 0.1–0.15 mg/kg orally on the first day post-transplant. Then, dose will be adjusted if needed to reach the desired trough level. Treatment is continued for one year.

Main outcome variables

Percentage of rejection-free patients between two groups (until one year after transplantation); Comparing the percentage of patient survival, graft survival, and mean trough concentration/dose of tacrolimus between two groups; Adverse events

General information

Reason for update

In the Exclusion Criteria section, the item “Patients who, at the time of entering the study (the end of the second

month after transplantation), have a glomerular filtration rate index greater than 30” was changed, given the course of the study, to the phrase “Patients who, at the time of entering the study, have a glomerular filtration rate index greater than 30.”

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N25**
Registration date: **2021-09-13, 1400/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-21, 1405/02/31**

Update count: **2**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Nassim Anjidani

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

Phone

+98 21 4347 3000

Email address

amini@orchidpharmed.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Open-label, randomized study to evaluate efficacy and safety of Suprotac® in comparison with Prograf® in liver transplant patients in Iran

Public title
Efficacy and safety evaluation of Suprotac® in comparison with Prograf® in prevention of liver transplant rejection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient aged between 18 to 70 years Ability to comprehend and willing to sign the informed consent form for this study

Exclusion criteria:
Use of other investigational drugs at the time or within 30 days of enrolment, or within five half-lives of those drugs, whichever is longer (except for dialysis-related drugs which are not expected to interact with the study regimens) Patients with contraindication for tacrolimus or any other ingredients of the formulation Patients with Glomerular Filtration Rate greater than 30 at the time of enrolment to the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **196**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be assigned to treatment using stratified block randomization with blocks of size 2 or 4. Randomization will be stratified according to living or deceased donors. The patients will be carried out using R-CRAN software version 3.6.3. Blocks will be made using permuted block randomization for a total of 196 patients (1:1 allocation ratio). The random series Excel will be placed in the patient recruitment center and a person will be responsible for assigning a random code by the investigator. This code will be assigned in order of entry and based on the stratification in which the patient's donor is living or deceased.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.SUMS.REC.1400.308

Health conditions studied

1

Description of health condition studied

Liver transplant

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes

1

Description

Transplantation rejection

Timepoint

All along the study duration until one year after transplantation surgery

Method of measurement

Liver transplant rejection approved by biopsy or clinical symptoms and laboratory tests (enhancement in alanine aminotransferase or aspartate aminotransferase liver enzymes)

Secondary outcomes

1

Description

Death

Timepoint

All along the study duration until one year after transplantation surgery

Method of measurement

Incidence of death written in the adverse event's section

of the case report form

2

Description

Graft loss

Timepoint

All along the study duration until one year after transplantation surgery

Method of measurement

Transplant rejection not responsive to the treatment according to the biopsy or clinical symptoms and laboratory tests (enhancement in alanine aminotransferase or aspartate aminotransferase liver enzymes)

3

Description

Mean trough concentration per dose of tacrolimus

Timepoint

Baseline, months 2, 4, 6 and 10

Method of measurement

Dividing trough concentration to the consumed daily dose

4

Description

Adverse events

Timepoint

Baseline, months 2, 4, 6 and 10

Method of measurement

All adverse events are assessed through patient reporting, physician diagnosis, or laboratory abnormalities, and are then classified by severity (based on Common Terminology Criteria for Adverse Events (CTCAE)), seriousness, relationship to the study drug, action taken, and outcome.

Intervention groups

1

Description

Intervention group: Suprotac® (Nanoalvand) is administered at a dose of 0.1–0.15 mg/kg orally on the first day post-transplant. Then, dose will be adjusted if needed to reach the desired trough level. Treatment is continued for one year.

Category

Treatment - Drugs

2

Description

Control group: Prograf® (Tacrolimus produced by Astellas Pharma) is administered at a dose of 0.1–0.15 mg/kg orally on the first day post-transplant. Then, dose will be adjusted if needed to reach the desired trough level. Treatment is continued for one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu-Ali Sina Hospital

Full name of responsible person

Dr Saman Nik-Eghbalian

Street address

2nd Phase, Sadra

City

Shiraz

Province

Fars

Postal code

7199467985

Phone

+98 71 3344 0000

Email

Nikeghbalian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nanoalvand Company

Full name of responsible person

Dr Nima Sepehri

Street address

No. 485, between 63th and 65th Ave., Yousef Abad

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8802 0579

Email

info@nanoalvand.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nanoalvand Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Orchid Pharmed

Full name of responsible person

Nassim Anjidani

Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No 42, Attar Neyshaboori St., Vanak Sq., Tehran

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Person responsible for updating data

Contact

Name of organization / entity

Orchid Pharmed

Full name of responsible person

Nassim Anjidani

Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Province

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Postal code

1994766411

Phone

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available