# 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**
Nassim Anjidani

**Position**
Medical Manager

**Latest degree**
Medical doctor

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## 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