

A safety and efficacy assessment of chimeric ribozyme to proliferating cell nuclear antigen to prevent recurrence of proliferative vitreoretinopathy

Submission date 23/08/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/02/2008	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.immusol.com/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IM-VIT 100-01 (IND # 63,756)

Study information

Scientific Title

Acronym

IM-VIT100

Study objectives

To determine the safety and efficacy of VIT100 (VitrenAse), a proliferating cell nuclear antigen (PCNA) ribozyme (Immusol, Inc. San Diego, CA), in preventing recurrent proliferative vitreoretinopathy (PVR) in patients with established PVR who undergo vitrectomy for retinal reattachment repair.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Columbia University Institutional Review Board reviewed and approved research on the 31st July 2003 (reference number: AAA8110).

Study design

Multicentre, double-masked, placebo controlled, randomised 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

Proliferative Vitreoretinopathy

Interventions

All patients undergo retinal reattachment surgery with pars plana vitrectomy. Additional intraoperative procedures including scleral buckle placement or revision, pars plana lensectomy or limbal cataract extraction, Intraocular Lens (IOL) implantation or removal, temporary

keratoprosthesis and penetrating keratoplasty, retinotomy, and/or gas or silicone oil tamponade could be performed at the discretion of the operating surgeon and required the assistance of an anterior segment specialist in certain cases.

All patients were to be randomly assigned to one of the three treatment groups: 0.75 mg or 0.15 mg VitrenAse and placebo (ratio 1:1:1). A single intravenous administration of VitrenAse or placebo was administered after the completion of the vitrectomy procedure.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

VitrenAse (VIT100)

Primary outcome measure

Efficacy variables included:

1. Failure rate of retina repair surgery secondary to PVR
2. All cause of failure rate of retina repair surgery
3. Retinal status

Secondary outcome measures

Safety variables included:

1. ETDRS best corrected visual acuity
2. Lens status
3. Intraocular pressure
4. Biomicroscopy findings
5. Adverse effects
6. Serum Blood Urea Nitrogen (BUN) and creatinine

Overall study start date

01/07/2002

Completion date

31/08/2004

Eligibility**Key inclusion criteria**

Patients with retinal detachment with Grade C or worse PVR who undergo vitrectomy for retinal reattachment:

1. Retinal detachment
2. Proliferative vitreoretinopathy (PVR) grade C or worse under direct visualisation
3. Visual acuity greater than no light perception
4. Aged at least 18 years
5. Patient willing and able to sign informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

170

Key exclusion criteria

1. Vision of no light perception
2. Presence of any uncontrolled, sight threatening concomitant eye disease
3. Severe non proliferative diabetic retinopathy or proliferative diabetic retinopathy according to Early Treatment Diabetic Retinopathy Study (ETDRS) criteria
4. Other pre-existing vaso-proliferative retinopathy
5. History of intraocular inflammatory disease
6. Retinoschisis detachment
7. Heredity vitreoretinopathies
8. Best corrected visual acuity less than 20/200 prior to onset of retinal detachment due to permanent pre-existing condition
9. Vision less than 5/200 or visual field less than 20 degrees in the fellow eye
10. Pregnant or nursing women or women of childbearing potential not using a reliable form of contraception
11. Concurrent participation in any other research study within 30 days of entry into the study

Date of first enrolment

01/07/2002

Date of final enrolment

31/08/2004

Locations

Countries of recruitment

United States of America

Study participating centre

635 West 165th Street

New York

United States of America

10032

Sponsor information

Organisation

Immusol, Inc. (USA)

Sponsor details

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United States of America
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+1 858 824 1100
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Sponsor type

Industry

Website

<http://www.immusol.com>

ROR

<https://ror.org/03q43d318>

Funder(s)

Funder type

Industry

Funder Name

Immusol, Inc. (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/09/2007		Yes	No