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

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
23/08/2006		☐ Protocol		
Registration date		Statistical analysis plan		
13/09/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/02/2008	Eve Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/03q43d318

Funder(s)

Funder type

Industry

Funder Name

Immusol, Inc. (USA)

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes