

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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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?
<a href="#">Results article</a>	Results	01/09/2007		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes