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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/09/2006	**Overall study status** Completed	
Last Edited 19/02/2008	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.immusol.com/

Contact information

Type(s)
Scientific

Contact name
Dr William Schiff

Contact details
635 West 165th Street
New York
United States of America
10032
+1 212 305 5922
wms13@columbia.edu

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
10790 Roselle Street
San Diego, CA
United States of America
92121
+1 858 824 1100
bsimon@immusol.com

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