

Ultrasound treatment for glaucoma

Submission date 04/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/12/2020	Condition category 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

Contact name
Dr Donald Schwartz

Contact details
2650 Elm Avenue #108
Long Beach
United States of America
90806
-
dschwartz@eyesonix.com

Additional identifiers

Protocol serial number
20091044

Study information

Scientific Title
A randomised controlled prospective study of the effect of topical application of ultrasound for glaucoma

Acronym
TUG

Study objectives

Low frequency ultrasound applied external to the limbus of the eye may induce a similar cytokine release to that of laser applied to the trabecular meshwork of the eye and thereby lead to a decrease in intra-ocular pressure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Western Institute Review Board approved on the 26th June 2009 (submission no.: e30817; study no.: 1109459; protocol ID: 20091044)

Study design

Randomised controlled prospective study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Open angle glaucoma

Interventions

Low frequency ultrasound application externally to the area adjacent to the limbus of the eye. Control is the other eye, where glaucoma is essentially equal - a coin toss determines which is the treated eye. The treatment is one session of approximately 10 minutes. The follow-up is for six months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Intraocular pressure changes, measured at one day, one week, one month, two months, three months and six months.

Key secondary outcome(s)

Tolerability to the intervention, measured at one day, one week, one month, two months, three months and six months.

Completion date

30/08/2010

Eligibility

Key inclusion criteria

1. Pre-existing glaucoma or ocular hypertension
2. Aged above 18 years, all genders welcome

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

26

Key exclusion criteria

Infants

Date of first enrolment

20/08/2009

Date of final enrolment

30/08/2010

Locations**Countries of recruitment**

United States of America

Study participating centre

2650 Elm Avenue #108

Long Beach

United States of America

90806

Sponsor information**Organisation**

Eye Sonix (USA)

ROR

<https://ror.org/04qqvwm35>

Funder(s)

Funder type

Industry

Funder Name

Eye Sonix (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	26/09/2014	29/12/2020	Yes	No