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Ultrasound treatment for glaucoma

Submission date 04/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/12/2009	**Overall study status** Completed	
Last Edited 29/12/2020	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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

Overall study start date
20/08/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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)

Sponsor details
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Sponsor type
Industry

Website
http://eyesonix.com/

ROR
https://ror.org/04qqvvm35

Funder(s)

Funder type
Industry

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