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The pharmacological basis for the increase in visual time constants induced by single oral doses of sildenafil

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 14/02/2020	**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

ClinicalTrials.gov (NCT)
NCT00463957

Protocol serial number
N0544183630

Study information

Scientific Title
The pharmacological basis for the increase in visual time constants induced by single oral doses of sildenafil

Study objectives
Is the reason that sildenafil (Viagra) causes an increase in the time that the back of the eye perceives a visual image caused by the drug inhibiting phosphodiesterase type 6 (PDE6) in the light receptors in the eye?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eye Diseases: Visual sense

Interventions
Sildenafil (Viagra) and similar drugs eg tadalafil are phosphodiesterase type 5 inhibitor drugs that have been widely used in the treatment of erectile dysfunction in humans. One of the possible side effects of sildenafil is changes in vision and previous studies have shown that sildenafil can increase visual time constants ie cause a small increase in the length of time that an image is perceived on the back of the eye (retina). This can lead to symptoms of changes in vision for the patient taking the drug.
It has been suggested that the change in vision caused by sildenafil may be due to inhibition of the phosphodiesterase type 6 (PDE6) receptor in the light receptor cells of the eye. Although sildenafil and tadalafil predominantly act to inhibit the PDE5 receptor, sildenafil also has a significant degree of action in inhibiting the PDE6 receptor, whereas tadalafil shows very limited inhibition of this receptor.
We hope to establish whether PDE6 inhibition is the mechanism of the increase in visual time constants caused by sildenafil by performing a series of computerised visual tests to measure visual time constants following dosing with single oral doses of sildenafil, tadalafil or placebo. If PDE6 inhibition is the mechanism of the increase in visual time constants, we should observe changes in the visual time constants with sildenafil, but not tadalafil or placebo.
12 healthy male volunteers aged 18-55 years will be recruited to take part in this study. Volunteers will attend for a screening visit at which written informed consent will be taken and inclusion and exclusion criteria will be checked. A brief medical history will be taken, blood pressure measured and 12-lead electrocardiogram (heart tracing) performed. Vision will be

tested to exclude colour blindness and a 20ml sample of venous blood will be taken for DNA analysis to look at differences in the PDE6 gene.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
sildenafil

Primary outcome(s)
Effects of the drugs on retinal time constants (visual persistence and reaction times)

Key secondary outcome(s))
1. Effects of drugs on retinal time constants in different types of photoreceptors
2. Effect of PDE6 genotype on drug effects on retinal time constants

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Healthy male subjects aged 18-55 years. We have decided to only recruit male volunteers because phosphodiesterase inhibitors such as sildenafil and tadalafil are almost exclusively used in male patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Male

Key exclusion criteria
1. Volunteers suffering from any significant medical or psychiatric illness. Subjects may be enrolled at the discretion of the principal investigator or his designated deputy if the illness

would not affect the validity of the study or pose an added risk to the subject (e.g. mild asthma, hay fever). Specific conditions that will exclude volunteers from taking part are as follows:
1.1 Cardiac disease
1.2 Blood pressure <90/50mmHg or >160/100mmHg on screening visit
1.3 Renal disease
1.4 Liver disease
1.5 Stroke
1.6 Sickle cell anaemia
1.7 Multiple myeloma
1.8 Leukaemia
1.9 Bleeding disorders
1.10 Peyronie's disease
1.11 Priapism
2. Subjects receiving prescribed medications. Subjects may be included if the medication prescribed would not be considered to affect the validity of the study or pose an added risk to the study subject (e.g. inhaled asthma therapy). Specific exclusions include the following (due to interaction with the study drugs): nitrates, nicorandil, alpha blockers, erythromycin, cimetidine, rifampicin, phenytoin, carbamazepine, Phenobarbital, ritonavir, saquinavir, ketoconazole, itraconazole.
3. Female subjects
4. Subjects with known visual abnormalities other than refractive errors, including specifically: retinitis pigmentosa, optic neuropathy

Date of first enrolment
24/06/2006

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK), Own Account NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration