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A randomised open label placebo study to evaluate the use of Solcogyn applied topically to the cervix in women referred for the assessment of cervical low grade intro-epithelial lesions

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2015	Urological and Genital Diseases	[_] Record updated in last year

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
N0106110085

Study information

Scientific Title
A randomised open label placebo study to evaluate the use of Solcogyn applied topically to the cervix in women referred for the assessment of cervical low grade intro-epithelial lesions

Study objectives
To determine if treatment of a cervical ectopy associated with minor cytological abnormalities but no colposcopic evidence of high grade dysplasia results in a better clearance rate in terms of normal cytology at 6 month follow up than in the placebo controlled group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open-label placebo study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dysplasia

Interventions
1. Placebo (saline)
2. Solcogyn

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
Increased number of patients returning to normal cytology after six months of treatment.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/03/2002

Completion date
19/09/2003

Eligibility

Key inclusion criteria
106 women aged 20-50 attending the colposcopy clinic with cytological abnormalities showing borderline or mild changes and who also have a cervical ectopy.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
106

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
19/03/2002

Date of final enrolment
19/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gloucestershire Royal Hospital
Gloucester
United Kingdom
GL1 3NN

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Gloucestershire Research and Development Consortium (UK)

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