ISRCTN47437431 https://doi.org/10.1186/ISRCTN47437431

An investigation into the effects of diindolylmethane (BioResponse DIM®) supplementation in women with low-grade cervical cytological abnormalities

Submission date
14/09/2005

Recruitment status
No longer recruiting

Registration date
25/10/2005

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-see-whether-a-dietary-supplement-can-affect-abnormal-cervical-cells

Study website
http://www.crisp-trials.org

Contact information

Type(s)
Scientific

Contact name
Prof Peter Sasieni

Contact details
Wolfson Institute
Queen Mary College
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 (0)207 014 0260
peter.sasieni@cancer.org.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00462813

Secondary identifying numbers
N/A

Study information

Scientific Title
An investigation into the effects of diindolylmethane (BioResponse DIM®) supplementation in women with low-grade cervical cytological abnormalities

Acronym
CRISP-1

Study objectives
DIM® will prevent progression and accelerate regression of cervical intra-epithelial neoplasia.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Cervical neoplasia.

Interventions

Double-blind, placebo-controlled trial. Randomisation is in the ratio 2 DIM®: 1 placebo. Diindolylmethane (BioResponse DIM® - 75 mg capsules) - two capsules daily for 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Reduction in cervical intra-epithelial neoplasia grade 2 (CIN2) or worse.

Secondary outcome measures
Cytology, lesion size, human papillomavirus (HPV) status (all at 6 months).

Overall study start date
25/10/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Women with a first mildly dyskaryotic smear or a second borderline smear taken within the Cervical Screening Wales (CSW) programme will be invited to participate in the trial.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3000

Key exclusion criteria
N/A

Date of first enrolment
25/10/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Institute
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary and Westfield College, University of London (UK)

Sponsor details
Joint R and D Office
3rd Floor Rutland House
42-46 New Road
London
England
United Kingdom
E1 2AX
+44 (0)207 882 7272
Helen.Cadiou@bartsandthelondon.nhs.uk

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (C8162/A4609).

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Plain English results				No	Yes
Results article	results	03/01/2012		Yes	No