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

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00462813

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)

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(s)
Reduction in cervical intra-epithelial neoplasia grade 2 (CIN2) or worse.

Key secondary outcome(s)
Cytology, lesion size, human papillomavirus (HPV) status (all at 6 months).

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
N/A

Date of first enrolment
25/10/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wolfson Institute
London
United Kingdom
EC1M 6BQ

Sponsor information

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

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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/01/2012		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes