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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
14/09/2005		☐ Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
25/10/2005		[X] Results			
Last Edited	Condition category	[] Individual participant data			
19/10/2018	Cancer				

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

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00462813

Protocol serial number

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Plain English results</u>				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes