

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2018	Condition category Cancer	<input type="checkbox"/> 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

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

ClinicalTrials.gov (NCT)

NCT00462813

Protocol serial number

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

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