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A placebo-controlled trial of nimodipine with cyclophosphamide/cisplatin for the treatment of advanced ovarian cancer

Submission date	Recruitment status	[ ] Prospectively registered
01/07/2001	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/07/2001	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/01/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G37

Study information

Scientific Title
A placebo-controlled trial of nimodipine with cyclophosphamide/cisplatin for the treatment of advanced ovarian cancer

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Ovarian cancer

Interventions
1. Arm A: Placebo tablet
2. Arm B: Nimopidine tablet

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1989

Completion date
01/01/1993

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of invasive epithelial ovarian cancer
2. International Federation of Gynaecology and Obstetrics (FIGO) stages Tc - Tv
3. 18-70 years old
4. Performance Status less than or equal to 2
5. White Blood Cells at least 4 x 10^9/l
6. Platelets at least 120 x 10^9/l
7. Creatinine or Ethylene Diamine Tetraacetic Acid (EDTA) clearance greater than or equal to 60 ml/min
8. Normal Bilirubin
9. Serum glutamic-oxaloacetic transaminase (SGOT)/Serum glutamic pyruvic transaminase (SGPT) less than or equal to twice normal limit
10. No previous chemotherapy or radiotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/01/1989

Date of final enrolment
01/01/1993

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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