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QUASAR (stands for QUick and Simple And Reliable). UKCCCR randomised study of adjuvant chemotherapy in colon and rectal cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Richard Gray

Contact details
University of Birmingham Clinical Trials Unit
University of Birmingham
Park Grange
1 Somerset Road
Edgbaston
Birmingham
United Kingdom
B15 2RR
+44 (0)121 415 9100
r.gray@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00005586

Secondary identifying numbers
G9436870/G9521239

Study information

Scientific Title
QUASAR (stands for QUick and Simple And Reliable). UKCCCR randomised study of adjuvant chemotherapy in colon and rectal cancer

Acronym
QUASAR

Study objectives
Reliable assessment, among patients who have undergone apparently curative surgery for colorectal cancer, of the balance of benefits and risks of adjuvant chemotherapy. Patients for whom there is substantial uncertainty whether or not they should receive chemotherapy are randomised between chemotherapy versus open control. Patients considered to have a clear indication for chemotherapy were randomised (until 1997) between different chemotherapy regimens. Of those who receive adjuvant chemotherapy, the four treatment regimens were:
1. 5-FU (370 mg/m^2) + 175 mg L-folinic acid + levamisole
2. 5-FU (370 mg/m^2) + 175 mg L-folinic acid + placebo
3. 5-FU (370 mg/m^2) + 25 mg L-folinic acid + levamisole
4. 5-FU (370 mg/m^2) + 25 mg L-folinic acid + placebo
given either daily for five days every four weeks for a total of six cycles, or once-weekly for thirty weeks. Since 1997 patients allocated chemotherapy all receive arm four (without placebo).

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

Health condition(s) or problem(s) studied
Colorectal Cancer

Interventions
Chemotherapy versus open control

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Chemotherapy: Fluorouracil, L-folinic acid and levamisole

Primary outcome measure
Survival, recurrence, cost-effectiveness, quality of life.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/1994

Completion date
31/10/2003

Eligibility

Key inclusion criteria
Patients who have had apparently curative surgery for Duke's A, B or C colorectal cancer within the past three months are eligible for inclusion in QUASAR.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
5000

Key exclusion criteria
There are no definite exclusion criteria but patients must be considered fit by their clinicians to undergo six months chemotherapy.

Date of first enrolment
01/05/1994

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2RR

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	06/05/2000		Yes	No
Results article	results	01/08/2000		Yes	No
Results article	results	15/12/2007		Yes	No
Results article	results	01/04/2011		Yes	No