

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

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/m²) + 175 mg L-folinic acid + levamisole
2. 5-FU (370 mg/m²) + 175 mg L-folinic acid + placebo
3. 5-FU (370 mg/m²) + 25 mg L-folinic acid + levamisole
4. 5-FU (370 mg/m²) + 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