The effect of rofecoxib on colorectal liver metastases

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/07/2001		[] Protocol		
Registration date	Overall study status	 [] Statistical analysis plan [X] Results 		
01/07/2001	Completed			
Last Edited	Condition category	Individual participant data		
04/01/2012	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr - -

Contact details UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers CRC COX2

Study information

Scientific Title

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 Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Colorectal cancer, liver metastases

Interventions 1. Rofecoxib 25 mg/day 2. Placebo

Intervention Type Other

Phase Not Specified

Primary outcome measure Not provided at time of registration

Secondary outcome measures Not provided at time of registration

Overall study start date 01/01/1998

Completion date

05/01/2002

Eligibility

Key inclusion criteria

1. Age greater than or equal to 18 years

2. Either sex

3. Liver resection deemed clinically appropriate for management of metastatic Colorectal Cancer (CRC) liver disease

- 4. Duration between decision to perform liver resection and surgery greater than 2 weeks
- 5. Ability to give written informed consent
- 6. Telephone at home

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants Not provided at time of registration

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/01/1998

Date of final enrolment 05/01/2002

Locations

Countries of recruitment England

United Kingdom

Study participating centre UKCCCR Register Co-ordinator 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 Industry

Funder Name Merck and Co Inc. (USA)

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?
<u>Results article</u>	results	01/09/2003		Yes	No