Quality of life in patients with advanced gastric cancer: a randomized trial comparing docetaxel, cisplatin and 5-fluorouracil against epirubicin, cisplatin and 5-fluorouracil

Submission date	Recruitment status No longer recruiting	Prospectively registered		
03/07/2006		☐ Protocol		
Registration date 28/07/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
25/09/2009	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Quality of life does not differ in advanced gastric cancer patients after receiving either docetaxel, cisplatin and 5-fluorouracil (5-FU) (TCF regiment) versus epirubicin, cisplatin and 5-FU (ECF-regimen).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Tehran University of Medical Sciences November 2001

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Gastric cancer

Interventions

Three to six cycles of either ECF (epirubicin 60 mg/m 2 , cisplatin 60 mg/m 2 and 5-FU 750 mg/m 2 /day as a five-day continuous infusion) or TCF regimen (docetaxel 60 mg/m 2 , cisplatin 60 mg/m 2 and 5FU in the same dose and schedule of ECF) every three weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Response rate

Secondary outcome measures

Quality of life and survival

Overall study start date

01/01/2002

Completion date

01/01/2005

Eligibility

Key inclusion criteria

Patients with histologically confirmed advanced gastric cancer

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

86

Key exclusion criteria

Patients with local or local-regional gastric cancer

Date of first enrolment

01/01/2002

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

Iran

Study participating centre

Cancer Institute

Tehran

Iran

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Sponsor information

Organisation

Tehran University of Medical Sciences (Iran)

Sponsor details

Enghelab Avenue Tehran Iran

info@sina.tums.ac.ir

Sponsor type

University/education

ROR

https://ror.org/01c4pz451

Funder(s)

Funder type

University/education

Funder Name

Tehran University of Medical Sciences (Iran)

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?
Results article	results	05/12/2006		Yes	No