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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
03/07/2006

Registration date
28/07/2006

Last Edited
25/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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
-

Sponsor information

Organisation
Tehran University of Medical Sciences (Iran)

Sponsor details
Enghelab Avenue
Tehran
Iran
-
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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