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Effectiveness of patient support programme for the treatment of hepatitis C

Submission date	Recruitment status	[_] Prospectively registered
03/05/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/06/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Shin-Hai Tsai

Contact details
Number 250 Wu-Xing Street
TAIPEI
Taiwan
110

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Since there is no hepatitis C vaccine available for primary prevention, health education is the most important control strategy in containing the impact of hepatitis C. The hypothesis of this study is that effective patient support programs could improve the compliance to treatment and outcome of hepatitis C patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The institutional review board approved the protocol and all patients provided a written informed consent. The date and reference number of ethical approval for our trial is 10/10/2004 and F-950208.

Study design
Interventional randomised controlled study

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
Chronic hepatitis C

Interventions
All patients who met these criteria randomly chose to be serviced in either of the following two groups:
Group 1 with public health nurse consultation in the outpatient clinic.
Group 2 was offered phone consultation via a health communication center whenever patients needed. Trained healthcare professionals including four nurses and one physician backup at the communication center made a series of structured, scheduled supportive phone calls to patients throughout their treatment period. Additional support was offered to patients to call the healthcare professionals at any time if they have questions. Treating physicians were notified periodically by the health communication center through built-in standardized reminder forms.

All patients were treated with standard therapy. Patients were followed up for 72 weeks. Demographic, laboratory, adverse events, dropout rate and cost data were collected and analyzed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Sustained virologic response (absence of detectable HCV RNA at the end of follow-up with PCR assay)

Secondary outcome measures
1. Serum alanine aminotransferase
2. Aspartate aminotransferase
3. Dropout rate (the number of patients who discontinued treatment prematurely or were lost to follow-up)

Overall study start date
01/01/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Adult patients who have never received interferon and who had at least 2000 copies of HCV ribonucleic acid per ml (RNA/ml) of serum with polymerase chain reaction (PCR) assay, serum aspartate aminotransferase (AST) above the upper limit of normal within six months before entry into study and a liver biopsy result consistent with the diagnosis of chronic hepatitis C.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
Patients with:
1. Neutropenia (<1500/ml of neutrophils)
2. Anemia (Hb <12g/dl of hemoglobin)
3. Thrombocytopenia (platelet <90000/ml)
4. Human immunodeficiency virus (HIV) infection
5. Decompensated liver disease
6. Serum creatinine >1.5 times the upper limit of normal

7. Poorly-controlled psychiatric disease
8. Unwilling to receive contraception

Date of first enrolment
01/01/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Taiwan

Study participating centre
Number 250 Wu-Xing Street
TAIPEI
Taiwan
110

Sponsor information

Organisation
Department of Health (Taiwan)

Sponsor details
Number 100 Aiguo E. Road
Jhongjheng District
Taipei
Taiwan
10092

Sponsor type
Government

Website
http://www.doh.gov.tw

ROR
https://ror.org/0225asj53

Funder(s)

Funder type
Government

Funder Name
Department of Health (Taiwan) (ref: DOH94-TD-B-111-002)

Funder Name
National Health Research Institute (Taiwan) (ref: NHRI-EX95-9106PN)

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