

Therapeutic vaccination in patients with chronic hepatitis C genotype 1 using four courses of 8 + 6 + 6 + 6 intramuscular injections of 50 µg E1y at 3 week intervals: a multicenter, 3:1 randomized, double-blind, placebo-controlled, parallel-group study over 157 weeks in 122 patients

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/09/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

T2S-918-HCV

Study information

Scientific Title

Study objectives

The following hypothesis will be tested: Null hypothesis: mean difference from baseline in liver histology (Ishak score) for the E1y treated patients = mean difference from baseline in liver histology (Ishak score) for the patients who received 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

Multi-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic hepatitis C (genotype 1).

Interventions

This is a prospective, 3:1 randomized, multicenter, double-blind, placebo-controlled, parallel-group study of four courses of 8 + 6 + 6 + 6 IM injections of 50 µg E1y over 157 weeks in 122 genotype 1 chronic hepatitis C patients.

E1y or placebo treatment was allocated 3:1 using a central randomization procedure. Approximately 90 patients will receive a first course of eight injections of E1y at 3-week intervals, followed by three courses of six injections of E1y at 3-week intervals. Approximately 30 patients will receive a first course of eight injections of placebo at 3-week intervals, followed by three courses of six injections of placebo at 3-week intervals. Four weeks after the last study drug injection an end-of-study liver biopsy will be performed.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Liver histology (Ishak score) difference from baseline.

Secondary outcome measures

1. Other histology assessments
2. Virological, immunological, and biochemical responses
3. Quality of life
4. Safety evaluation

Overall study start date

09/01/2004

Completion date

31/05/2007

Eligibility**Key inclusion criteria**

1. Male and female patients 18 to 70 years old with compensated chronic hepatitis C genotype 1 infection
2. Female patients of childbearing potential should use an efficient method of contraception
3. Patients should either have failed to respond to interferon (IFN)-based therapy or have contraindications to IFN-based therapy or have decided not to start IFN-based treatment (after having been well informed)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

122

Key exclusion criteria

1. Prior (within last 3 months) or planned concomitant use of other hepatitis C treatment, immunosuppressive, or hepatotoxic treatment
2. Malnutrition or severe medical conditions or medical conditions associated with immunosuppression, including end stage renal failure or cancer
3. Severe symptomatic cryoglobulinemia, active autoimmune hepatitis, uncontrolled diabetes, or uncontrolled thyroid disease
4. HIV infection, active hepatitis B infection
5. Alcohol or intravenous drug abuse during the last year
6. Ongoing medical condition associated with chronic liver disease other than hepatitis C

Date of first enrolment

09/01/2004

Date of final enrolment

31/05/2007

Locations**Countries of recruitment**

Belgium

Study participating centre

UCL St Luc

Brussels

Belgium

1200

Sponsor information**Organisation**

Innogenetics NV (Belgium)

Sponsor details

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Sponsor type

Industry

Website

<http://www.innogenetics.be>

ROR

<https://ror.org/003dqcp70>

Funder(s)

Funder type

Industry

Funder Name

Innogenetics NV (Belgium)

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