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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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
15/09/2009

Condition category
Infections and Infestations

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

Protocol serial number
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

Study type(s)
Treatment

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(s)

Liver histology (Ishak score) difference from baseline.

Key secondary outcome(s))
1. Other histology assessments
2. Virological, immunological, and biochemical responses
3. Quality of life
4. Safety evaluation

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/003dqcp70

Funder(s)

Funder type
Industry

Funder Name
Innogenetics NV (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration