Summary

Title of Study:

Prospective evaluation of the performance of the HepIFN-Test for predicting response to therapy with pegylated interferon α and ribavirin in patients with chronic hepatitis C.

Indication:

Patients with chronic hepatitis C.

Investigator(s):

Markus Heim and Swiss Association for the Study of the Liver (SASL)-Investigators.

Objectives:

Primary:

To determine the positive - and the negative predictive value of the HepIFN-Test predicting the final treatment outcome (sustained virological response versus non-response/relapse).

Secondary:

1. To determine the positive and negative predictive value , and the sensitivity and the specificity of the HepIFN-Test for week 4 response during treatment with pegylated interferon α and ribavirin (RVR versus non-RVR).
2. To determine the positive and negative predictive value, and the sensitivity and the specificity of the HepIFN-Test for week 12 response during treatment with pegylated interferon α and ribavirin (cEVR/EVR versus non-response).
3. Assess the quality of the biopsy material and the performance of the HepIFN-Test in the real life situation of patients treated in a clinical routine setting in Switzerland.

Exploratory:

1. To perform an exploratory pharmacogenomics (mRNA) analysis with the aim to identify additional and potentially better transcript based biomarkers by splitting the main study in the a first discovery phase (first 20 patients) and a second validation phase (next 90 patients).
2. To perform an exploratory pharmacogenetic (DNA polymorphism) assessment, examining whether genetic variation in host genes (e.g., IL28B) is associated with differential response to interferon and ribavirin therapy.

3. To analyse microRNA (miRNA) expression profiles with the aim to identify additional and potentially better biomarkers for prediction of treatment response.

Study design and methodology:

1. Liver biopsies and blood will be collected for pharmacogenomic (mRNA) and pharmacogenetic assessments.
2. The treatment outcome is monitored in the participating centers, and the data is sent to the principal investigator.
3. Correlation between treatment outcome and results from pharmacogenomic and pharmacogenetic assessments will be done, and the performcance of the test evaluated.

Number of patients:

110 patients will be recruited.