

# RESEARCH – DEVELOPMENT REPORT

**Project name:** Non-alcoholic fatty liver, viral C hepatitis and gallstone disease – components of the metabolic syndrome. Clinical epidemiology, pathogenesis, non-invasive diagnosis, FINALISM

**Stage II:** Invasive and non-invasive means of diagnosis and staging the NAFLD. Initiation of the epidemiological study. The study of gall bladder motility in patients with NAFLD and MS. A retrospective study for comparative analysis of the invasive and non-invasive method for grading and staging of chronic viral hepatitis C.

**Reported period: 16.11.2006 – 30.04.2007**

## **I. Activity description:**

**Key words and descriptors:** Non-alcoholic Fatty Liver Disease (NAFLD), C viral hepatitis and gallstones disease (GD), metabolic syndrome, clinical epidemiology, pathogenetical aspects, non-invasive means of diagnosis, clinic, echographic and biologic screening, gall bladder motility, study database.

### **Activity II.1:**

In this activity of data storage for the comparative analysis of the morphologic invasive and biologic non-invasive means of diagnosis and staging of the NAFL, have been made morphological evaluations (liver biopsy), biological parameters evaluations and high resolution echography.

Based on the analysis of the obtained data it was possible to define the structure of biologic and image data basis; the serum deposit has been formed. Moreover, there have been created software modules necessary to obtain imagistic computerized methods applicable in the diagnosis and staging of NAFLD and viral chronic C hepatitis:

In order to accomplish all the targets foreseen in AII.1:

- There have been identified patients with NAFLD on the basis of clinic, imagistic and biologic study protocols;
- Invasive morphologic evaluation have been carried out on patients with NAFLD and the data have been stored for comparative analysis;
- The serum deposit has been founded for non-invasive evaluation of steatosis and fibrosis and the identification of some of the pathogenetic mechanisms involved in generating a NAFLD;

- High resolution echographies have been carried out on biopsied patients with NAFLD and the obtained data have been stored in the image data basis;
- On the basis of mathematical modeling techniques there have been elaborated a set of computerized imagistic methods (software modules);
- The control group has been formed in order to obtain the data according to which the biologic and imagistic results are being reported;
- The motility study of the gallbladder has been initiated on the patients with NAFLD echographically diagnosed.

### **Activity II.2:**

A retrospective study for comparative analysis of the invasive and non-invasive method for grading and staging of chronic viral hepatitis C.

1. The examination of the serum deposit and the morphological data base so that the retrospective study can be carried out.
2. The creation of the technological platform to determine the non-invasive markers.
3. The comparative analysis of the morphological exploration through liver biopsy with non-invasive biological data on the basis of the FibroTest and ActiTest patient protocol.
4. The accomplishment of the complete statistical processing and the elaboration of the material that is meant to be published.

### **II. Results:**

(Nominating the quantifiable results / technical, economical, social indicators – economic effects):

- The data base has been completed for the investigation of the invasive and non-invasive biological parameters in order to characterize the NAFLD and to test the imagistic methods that make it possible to differentiate the fibrosis from steatosis and also to determine the stage of the fibrosis.
- The retrospective study has been conducted on the diagnostic value of the non-invasive biological markers of hepatic fibrosis in chronic viral C hepatitis. Afterwards releasing the results so as to replace the invasive parameters that include hepatic biopsy with non-invasive procedures.

- The gallbladder motility study has been started.
- The computerized imagistic methods have been elaborated and the software module has been created.
- The intermediary rapport of activities that includes the technical-economical feedback of the stage.

### **III. Expected effects:**

By stocking the morphological, biological and imagistic data and by creating the database it can be achieved the final targets: comparative analysis of the invasive and non-invasive means of diagnosis and the identification of the pathogenetic mechanisms.

The retrospective study regarding the invasive and non-invasive means of diagnosis of the degree and stage of C Viral Hepatitis makes it possible to recognize the equivalency between the two types of analysis and it can also determine the eligibility for the antiviral treatment of the patients with chronic C hepatitis without the need of invasive explorations.

### **IV. The stage of accomplishing the planned aim:**

The purposes for this stage have been entirely accomplished in due time.

The activities intended for this phase have concretized by:

- Identifying the NAFLD in the metabolic syndrome on a hospital population of about 3000 patients.
- Creating the morphological data base which will evolve in the next stages.
- Creating the serum bank for the non-invasive explorations and to identify some pathologic links, deposit that will be completed in the next stages.
- Improving the centre in order to realize the technical platform necessary to obtain the biological results and including them in the FibroTest and ActiTest algorithm.

- Creating the software modules for image analysis.
- Comparative analysis throughout a retrospective study of the value of invasive and non-invasive means of grading and staging the NAFLD.

### **V.1 Other published articles:**

1. Grigorescu. M, Rusu M, Neculoiu D, Radu C, Serban A, Catanas M, Grigorescu MD The FibroTest Value in Discriminating between Insignificant and Significant Fibrosis in Chronic Hepatitis C Patients. The Romanian Experience. J Gastrointestin Liver Dis. 2007;16:31-37.
2. M. Grigorescu, Mihaela Rusu, Corina Radu, Daniela Neculoiu, A. Șerban, Erica Chiorean, M.D. Grigorescu. The value of alfa-2 macroglobuline and haptoglobine in diagnosis of hepatic fibrosis. Clujul Medical. 2006; LXXIX: 544-553.
3. Mihaela Rusu, M. Grigorescu. Hepatic fibrogenesis. Clujul Medical. 2006; LXXIX: 529-538..

### **V.2 Articles that are going to be published (april 2007):**

1. Monica Lupșor, Radu Badea, Horia Ștefănescu. New perspectives in the noninvasive evaluation of liver fibrosis: ultrasonic transient elastography (FibroScan®). Romanian Journal of Hepatology. 2007 (în curs de publicare) Romanian Journal of Hepatology 2006; 2 (1): 97-98

### **VI. Scientific communication:**

1. Monica Lupșor. „Sistem inteligent de detectare și evaluare neinvazivă a fibrozei, restructurării și a nodulilor displazici ai ficatului cu ajutorul ultrasonografiei 2D/3D și a markerilor moleculari”- lucrare prezentată în cadrul Seminarului anual al Centrului de Formare în Ultrasonografie, organizat cu ocazia zilelor UMF, 8 dec 2006, Cluj-Napoca
2. Monica Lupșor, Radu Badea, Horia Ștefănescu, Sergiu Nedevschi, Delia Mitrea, Titus Suteu. „Aportul ultrasonografiei convenționale și a tehnicilor computerizate de analiză a imaginii în evaluarea fibrozei și restructurării hepatice” – a IV-a ediție a manifestărilor Maramedica, Baia Mare, 8-10 februarie 2007

