

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 I: Clinical, echographical and biological screening. Initiating the bladder motility study.

Reported period: 01.09.2006 – 15.11.2006

I. Activity description:

Key words and descriptors: non-alcoholic fatty liver disease (NAFLD), viral C Hepatitis, gallbladder disease, metabolic syndrome, clinical epidemiology, pathogenetic aspects, non-invasive procedures of diagnosis, clinical, echographical and biological screening, gallbladder motility, studies protocols.

Activity I.1:

1. Elaborating the studies protocols:
 - a. Extensive documentation from specialized literature regarding to the prevalence and pathogenesis mechanisms of NAFL and GD and the metabolic component of chronic viral C infection.
 - b. Comparative research of the non-invasive biological (Fibro Test, FibroSpect) or imagistic (Fibro Scan) tests, in comparison to the invasive morphological exploration (hepatic biopsy).
 - c. Diverse investigations methods identification: clinical, biological, imagistic, morphologic and epidemiologic which will be used in the actual study.
 - d. Personal studies protocols elaboration on documentary basis: clinic, biologic, morphologic, epidemiologic, imagistic.
 - e. Determination of the NAFL and GD study algorithm and the digestive components of the metabolic syndrome, and also the metabolic component of viral C Infection.
2. Training the observatory and research personnel in order to achieve the necessary knowledge about the study algorithm and the primary information gathering process so that it can be introduced in the study data sheets files.

3. Setting the high resolution echograph in order to capture echographical images which can offer a great quantity of information for the computerized processing and also real time verification of the settings.
4. Determine the specifications of the computerized system for hepatic texture analysis.

Activity I.2:

Starting a clinical, echographic, virologic and biologic screening in order to determine the prevalence of NAFL and GD in hospital population.

Determining the necessary number of patients in order to meet the criteria for a correct epidemiologic study (error risk 5%).

Providing the necessary technology for the echographic screening and new working areas.

Training the personnel that do the echographic screening on how to standardize the quantitative elements and how to appreciate the qualitative data. All this taking place under the surveillance of instructors experts in ultrasounds.

Elaboration of the data sheets form.

Advising the observer personnel and the researchers regarding the filling process of the data sheets forms and the ways in which the data should be introduced.

Checking whether the primary data has been correctly filled into the questionnaire forms and the validity of the forms.

Start out the ultrasonic screening on the hospital population so that it can be established the prevalence of the NAFL and GD in the MS.

A study on the computerized methods of analysis and processing of the ultrasonic images.

Results:

(nominating the quantifiable results / technical, economical, social indicators – economic effects registered at the CD unit):

The research report contains:

- Clinical study protocol
- Biological study protocol
- Imagistic study protocol
- Morphologic study protocol
- Epidemiologic study protocol
- Computerized entry system specifications
- Study data sheets;
- A study about the methods of analyzing and processing the ultrasonic images
- Setting out the screening on a group of patients

Intermediary activity report that includes the technical-economical feedback of the stage.

Expected effects:

The project will provide data with reference to the predominance of the digestive components (NAFLD and GD) in the MS, it will mention some of the pathogenetical links of their determination and it will bring arguments so as to implement the non-invasive means of diagnosis, therefore reducing the costs, diminishing the potential complication rate and enhancing the life quality of the patients.

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:

- creating and elaborating the algorithm of the complex clinical, biological, morphological, imagistic study;
- elaborating the detailed protocols for the clinical, biological, morphological, imagistic and epidemiological study;
- providing the centre with means for the imagistic study in order to initiate the ultrasonic screening;
- setting the device for high resolution echography;
- establishing the specifications for the computerized system;

Other articles:

1. Grigorescu M. Noninvasive biochemical markers of liver fibrosis. J Gastrointestin Liver Dis. 2006; 15(2), 149-159.
2. Grigorescu M, Rusu M, Radu C, Grigorescu MD. Liver biopsy in viral C chronic hepatitis. Are there any non-invasive possibilities? Clujul Medical. 2006; LXXIX(3): 271-279.
3. Grigorescu M. Non-invasive evaluation of hepatic fibrosis. Gastro.ro. 2006 nr.3: disponibil la <http://presspro-gastro.ro/articole/evaluati-162.php>
4. Lupșor M, Badea R, Nedevschi S, Mitrea D, Florea M. Ultrasonography contribution to hepatic steatosis quantification. Possibilities of improving this method through computerized analysis of ultrasonic image. IEEE-TTTC International Conference on Automation, Quality and Testing, Robotics. 2006 vol. II: 478-483

Articles appeared in resume volumes:

1. Lupșor M, Sergiu Nedevschi, Delia Mitrea, Radu Badea. „Computerised modalities on evolution of hepatic steatosis” Revista romana de Ultrasonografie 2006; 8(1): 103
2. Lupșor M, Nedevschi S, Mitrea D, Tripon S, Badea R. Ultrasonography aspects of steatosis in diabetes mellitus patients. Assessment methods of the evolution through computerized analysis of the ultrasonic image. J Gastrointestin Liver Dis. 2006; 15(suppl 1): 119-120

3. Lupsor M, S Nedevschi, Delia Mitrea, T Suteu, Mira Florea, R Badea. Approach regarding hepatic steatosis evolution on patients with diabettus mellitus. Romanian Journal of Hepatology 2006; 2 (1): 88-89

4. Simona Tripon, M Grigorescu, Dana Damian, A Serban, Monica Lupsor, R Badea. He patic steatosis: clinical, US and hystological approach. Romanian Journal of Hepatology 2006; 2 (1): 97-98

Scientific communication:

- Grigorescu M. News in diagnosis and treatment of chronic viral hepatitis. Sighisoara, 5-7 mai 2006
- Grigorescu M. Liver in metabolic disease. Al XVI-lea Congres National de Hepatologie 22-23 sept 2006, Bucuresti
- Grigorescu M. Hepatic fibrosis. Al XXVII-lea Simpozion National de Gastroenterologie, hepatologie si Endoscopie Digestiva, 14-17 iunie 2006, Poiana Brasov