

CLINICAL TRIAL SYNTHESIS AND ANALYSIS

Dr Richard Clement

Medical Doctor

The 08.08.2007

Pre-study IGR 2002:

Validation of:

- Visualization and evaluation of the pains

Summary

A group of 39 patients who had chemotherapy treatment was measured with the EIS system at Gustave Roussy Institute (IGR) in France, in order to investigate the specificity of a graphic called the ElectroScanGram (ESG).

The hypothesis of this pre study was:

1. For the subject's database, would the ESG graphic offer the possibility of being a marker for the pain visualization and pain follow up?

This first hypothesis was validated by these 3 factors:

- The specificity and sensibility of ESG graphic

After statistical study of the base by the statistical method Mean Plot: Whisker using STATISTICA version 6.0, it appeared that the ESG graph presented a level of sensitivity of 100% (IC calculated at 95%) compared to the reference base and a level of specificity of 89% (IC calculated at 95%).

- The acid base balance of interstitial fluid

The interstitial fluid had an average database pH of 7.41 (norms: 7.33)

- The tissue parameters (tissue oxygen)

The tissue oxygen is reducing: 67 mm /Hg (norms: 80 mm/Hg)

2. Is the number of patients of this study was sufficient for statistical analysis in order to calculate a level of specificity for the ESG graphic?

This second hypothesis is validated for the calculation of the specificity.

Key words: Pains- EIS device. ESG Graph - sensitivity of 100% (IC calculated to 95%) and a specificity of 89% (IC calculated to 95%) – Interstitial fluid alkalosis-Tissue hypoxia – Help for determination of the number of patients for future clinical investigations

Clinical investigation Botkin Hospital 2003

Validation of:

- Inverse problem for the modeling of human body EIS
- Marker of unipolar depression : estimation of interstitial fluid cerebral serotonin level
- Marker of hypothyroid: estimation of thyroid production (T3)
- Screening and follow up of:
 - Hypertension:
 - Arrhythmia:
 - Type I Diabetes:
 - Hepatitis, viral ABC:
 - Heart attack:
 - Circulatory problems:
- Follow up:
 - Spasmodic colitis:
 - Gastritis:
 - Duodenal ulcer:
 - Angina:
 - Type II Diabetes :
 - Pancreatitis:
 - Hepatitis, alimentary:
 - Chronic bronchitis and asthma:
 - COPD:
 - Cancers:

Summary

The clinical tests undertaken at Botkin Hospital with the aid of the EIS system on 589 patients comprising a panel of 20 groups (1 control group of healthy subjects and 19 groups of patients presenting different diagnosed pathologies) allowed the system to acquire new algorithms for inverse problems necessary for the human body modeling EIS. .

The hypotheses tested were:

1. Could the ESG graphic be a marker of certain pathologies?

Results:

The EIS examination was able to be validated as a marker of certain pathologies:

- Neurological diseases (unipolar depression)
- Hypothyroid

This hypothesis was validated by the specificity and the sensitivity of the ESG graph:

For unipolar depression: After statistical study of the base by the statistical method Mean Plot: Whisker using STATISTICA version 6.0, it appeared that the ESG graph presented a sensitivity of 85% (IC calculated at 95%) compared to the reference base and a specificity of 95 % (IC calculated at 95%).

For hypothyroid: After statistical study of the base by the statistical method Mean Plot: Whisker using STATISTICA version 6.0, it appeared that the ESG graph presented a

sensitivity of 82% (IC calculated at 95%) compared to the reference base and a specificity of 92 % (IC calculated at 95%).

And therefore, the ESG graph by the values of the volumes 1, 3,9,16 could estimate the level of interstitial cerebral serotonin and the volumes 11 and 12 could estimate the thyroid production (T3)

However, due to a lack of sensitivity it could not be validated in the case of other pathologies as much as a marker, but due of high specificity it could be validated in screening and /or follow up of pathologies.

2. Could the ESG graphic help for the localisation of organs in the modeling and create new algorithms by application of inverse problem.

The results of these clinical tests combined with direct methods (Venn diagram mathematical calculation) led to definition of the localization of organs at the level of modeling which the EIS system considers. The only subtle point remains the distinction at the level of different organs of the digestive system.

Key words

Algorithms of inverse problems- marker of neurological diseases- Screening- Follow up-modeling

Investigation Marfino

Main objective: Validation of:

- Calculation of the value of the interstitial Ionogram
- Fat mass measurement validation

Second objective

Research of algorithms for statistical estimation of blood biochemical constants (Atherogenic Index, Glucose, Urea, Creatinine, Triglycerides) for the subjects not in current medication.

During the time of the 07 07. 2004 to the 20.08.2004, 2 groups of patients were examined:

Group 1:

58 healthy subject for estimate the body fat mass of percentage.

25 men and 33 women, age was range of 17 and 69 and the age average is 42

Group 2:

33 patients with various diseases (or risk factors) or dysfunctions underwent rehabilitation cure in the Medicine scientific center of rehabilitation Marfino.

16 men and 17 women. Age was range of 42 and 71 and the age average being 47.

This clinical investigation is made for estimate the validity of the EIS system claims:

Claim 1: Estimate of the values of the interstitial ionogram

Claim 2: Calculation of the percentage of the fat mass

Criterion of main judgement

- Between the results of the statistical analysis of the risk I of program EIS and the real risk of the patient established by the conventional examinations. At least the correspondence must be 80% with the confidence interval calculated at 95%
- Between the results of percentage of the fat mass EIS and the results obtained according to the device: AVITA BF 1 BODY ANALYZER. The difference of value can not exceed 5%

Hypotheses:

EIS can be validated in its claim 1

And /or EIS can be validated in its claim 2

EIS cannot be validated in its claim 1 and 2

Concerning the claim 1 of EIS system , , it appears that in 33 patients of group 1, the statistical program (STATISTICA version 7.0) have analysing the correlation between EIS software and the laboratory tests and the correspondence is 89% with a confidence interval at 95% in ionogramme according to the difference of concentration between the plasma and the interstitial fluid.

The hypothesis 1 is validated for ionogram

Concerning the claim 2 of EIS system, it appears clearly that on the 58 patients of group 2, the EIS software gives results in conformity (standard deviations < to 5% with a confidence interval at 95%) to the AVITA BF1 device .

The hypothesis 2 is validated.

Key words

Validation of correspondence of direction of interstitial and blood ionogram- statistical estimation of blood biochemical constant- Fat mass estimation

Pre- study St Louis Hospital 2005

Validation of:

- Measurement of stress and catecholamine

Summary

A test group of 37 male patients with erection disorders (ED) were consulted with in the urology department at St. Louis hospital France.

All these patients had no treatment and presented a neurovegetative dystonia with an important stress and undoubtedly an important catecholamine rate.

They do not have any treatment and no pathology.

The objective was to test the specificity of a graph called the ElectroScanGram (ESG) generated by a device called The EIS System in a patient's database with erectile dysfunction (ED) related with a stress.

After a statistical study of the database (Mean Plot: Whisker using STATISTICA version 6.0), it indicated that the ESG graph had in 4 values (value 2, 4, 15 and 17) a sensitivity of 100 % (IC calculated to 95%) compared to the reference graph provided by the designer of the system, with a specificity of 87 % (IC calculated to 95%) .

The hypothesis of this pre study was:

1. Would the ESG graphic can be marker of the stress and neurovegetative dystonia?

This hypothesis is validated by the statistical results:

After a statistical study of the database (Mean Plot: Whisker using STATISTICA version 6.0), it indicated that the ESG graph had in 4 values (value 2, 4, 15 and 17) a sensitivity of 100 % (IC calculated to 95%) compared to the reference graph provided by the designer of the system, with a specificity of 87 % (IC calculated to 95%) .

2. Is the number of patients of this study was sufficient for statistical analysis in order to calculate a level of specificity for the ESG graphic?

This second hypothesis is validated for the calculation of the specificity. For more precision about the sensitivity, a meta analyses is necessary.

Key words: Andrology- EIS device. ESG Graph – Erectile dysfunction (ED) - Stress- Catecholamine- Neurovegetative dystonia- sensitivity of 100 % (IC calculated to 95%) and a specificity of 87 % (IC calculated to 95%) - determination of the number of patients for future clinical investigations.

Clinical investigation Botkin hospital 2006

Validation of:

- Validation for screening of 4 pathologies:
 - Hypothyroid
 - Hyper pressure
 - Atherosclerosis
 - Unipolar depression
- Validation for the follow up for 4 pathologies
 - Hypothyroid
 - Hyper pressure
 - Atherosclerosis
 - Unipolar depression
- Validation of production of thyroid (correspondence value of thyroid modeling / TSH laboratory test)

Summary

Clinical investigations were performed at the S.P. Botkin Hospital from May 20, 2006 to September 1, 2006 in order to evaluate the claims and intended use of the EIS system:

Claim 1: Statistical functional risks analysis offering assistance to medical diagnosis and the prescription of supplementary targeted examinations.

Claim 2: Therapeutic follow up:

Following approval by the Ethic Committee and in line with the Declaration of Helsinki, the tests were run without any accident or side effect, according to the proposed protocol (PIC TC 02).

215 subjects were recorded with the EIS system. These patients presented affections diagnosed by supplementary and conventional examinations (thyroid hypo function, hypertension, atherosclerosis and unipolar depression) and were taking no treatment. Recruitment had been decided upon before the tests began. The EIS system's program of analysis proposed a functional risk according to a scale from I to IV and supplementary examinations. Results took into account the risk scale and the conventional exams recommended by the system, in order to evaluate it in the claims of an aid to medical diagnosis

The treatments corresponding to the diseases were decided upon by the system, following patient registration, and a follow-up was undertaken every 15 days, on one hand with EIS system registrations and on the other by conventional methods.

Hypothesis tested were:

Would The EIS system be validated in claim 1?

The first hypothesis was validated:

Results showed the system's interest as an aid to medical diagnosis with a proposition for supplementary examinations of over 90%

Would The EIS system be validated in claim 2?

The second hypothesis was validated:

The EIS system had a remarkably reliable therapeutic follow-up in correlation with conventional exams and with the organic target of target of the medications.

The graphics of the values of the modeling of the thyroid and the TSH measurement in laboratory test, are showing a correspondence of results.

Key words: EIS – Targeted supplementary exams – Therapeutic follow-up

ADHD children 2007 Dr.Caudal Frederique

Validation of:

- Marker of ADHD
- Measurement of dopamine

Summary

Clinical trials were undertaken at the office of Dr. Frederique Caudal, Pediatrician and specialist of Attention-Deficit / Hyperactivity Disorder (ADHD) children.

This affection is related with a high level of cerebral dopamine.

The diagnosis of ADHD children is symptomatic with a dramatic possibility of error leading to a treatment (Ritalin[®]) associated with numerous side effects.

For this reason, a new measurable and therefore, objective diagnostic approach, was proposed using the electro medical system called EIS to complete the symptomatic diagnosis.

Data from fifty-nine children presenting symptoms and without treatment were recorded by the EIS system. This base was compared to another base of non-hyperactive children also recorded by the same EIS system.

The hypothesis tested was:

Can the EIS system by recording of the ESG graph be a marker of ADHD children?

This hypothesis was validating by statistical analysis:

It appeared following statistical analysis of the base (STATISTICA) that the ESG (Electro Scan Gram) graph generated by the EIS system presented a specificity of 95% (CI calculated at 95%) and a sensitivity of 93% (CI calculated at 95%) compared to a base of non-hyperactive children.

In view of the results, the ESG graph generated by the EIS system may be considered as a marker of ADHD children and a marker of the cerebral dopamine level.

KEYWORDS: EIS system- ADHD children- ESG (Electro Scan Gram)- specificity of 95% (CI calculated at 95%) , sensitivity of 93% (CI calculated at 95%)- ESG graph marker of ADHD children- Marker of cerebral dopamine level.

ANALYSIS

The EIS system is validated:

Pre-study IGR 2002:

Validation of:

- Visualization and evaluation of the pain

Clinical investigation Botkin Hospital 2003

Validation of:

- Inverse problem for the modeling of human body EIS
- Marker of neurology diseases: estimation of interstitial cerebral serotonin level
- Marker of hypothyroid: estimation of interstitial thyroid production
- Screening and follow up of:
 - Hypertension: 80%
 - Arrhythmia: 80%
 - Type I Diabetes: 68%
 - Hepatitis, viral ABC: 68%
 - Heart attack: 67%
 - Circulatory problems: 65%
- Follow up:
 - Spasmodic colitis: 63%
 - Gastritis: 63%
 - Duodenal ulcer: 60%
 - Angina: 59%
 - Type II Diabetes : 59%
 - Pancreatitis: 58%
 - Hepatitis, alimentary: 45%
 - Chronic bronchitis and asthma: 34%
 - COPD: 30%
 - Cancers: 20%

•

Investigation Marfino

Validation of:

- Value of the interstitial Ionogramme
- Statistical estimation of blood biochemical constants (Atherogenic Index, Glucose, Urea, Creatinine, Triglycerides) for the subjects not in current medication.
- Fat mass measurement validation

Pre- study St Louis Hospital

Validation of:

- Measurement of stress and catecholamine

Clinical investigation Botkin hospital 2006

Validation of:

- Validation for screening of 4 pathologies:
 - Hypothyroid

- Hyper pressure
 - Atherosclerosis
 - Unipolar depression
- Validation for the follow up for 4 pathologies
 - Hypothyroid
 - Hyper pressure
 - Atherosclerosis
 - Unipolar depression

- Validation of the measurement of interstitial production of thyroid (correspondence value of thyroid modeling / TSH laboratory test)

ADHD children 2007 Dr.Caudal Frederique

Validation of:

- Marker of ADHD
- Estimation of interstitial cerebral dopamine