PROTOCOL

EGERS

European Geriatric Emergency Departments Registry Study

On Behalf of the Geriatrics EuSEM Interest Group and the EUSEM Research committee

Protocol Number: .....

Status: Version 2.3

Date: 20/09/2020

EGERS

STUDY PROTOCOL

PROTOCOL NUMBER: ....

TITEL:

The European Geriatric Emergency Departments Registry Study

PROMOTER:

European Society of Emergency Medicine (EuSEM).
The EuSEM office is located at:
Antwerpsesteenweg 124 B27
B-2630 Aartselaar, Brussels
Belgium

STUDY COORDINATORS:

Principal Investigator: Assoc Prof Dr Mehmet Akif KARAMERCAN, Gazi University Faculty of Medicine Emergency Medicine Department, Ankara/TURKEY (EuSEM Research Committee Member)

Co-Principal Investigator: Assoc Prof Dr Zerrin Defne DÜNDAR, Konya/TURKEY (EuSEM Research Committee Member)

EGERS Steering Committee:

Chair: Mehmet Akif KARAMERCAN (Turkey)
Co-Chair: Zerrin Defne DÜNDAR (Turkey)

AND COUNTRY PI of THE STUDY

TECHNICAL SECRETARY:

EuSEM Research Committee

1. SUMARY

1. STUDY PROMOTER
   European Society of Emergency Medicine (EuSEM).
   The EuSEM office is located at:
   Antwerpsesteenweg 124 B27
   B-2630 Aartselaar, Brussels
   Belgium

2. STUDY TITEL
   The European Geriatric Emergency Departments Registry Study (EGERS Study)

3. STUDY CODE
   EuSEM …….

4. RESEARCHERS
   Physicians of each participating center.

5. PARTICIPATING CENTRES
   European Emergency Departments (EDs)

6. EVALUTED BY ETHICAL COMMITTEE
   Local Ethical Committees.

7. MONITOR RESPONSABLE
   Non applicable.

8. TREATMENT
   Non applicable.

9. PHASE OF STUDY
   Non applicable.

10. STUDY OBJETIVE

Principle Objective: Description of Epidemiologic and Age Related Characteristic of geriatric patients presenting to the ED

Secondary Objective: Determination of the prognostic and predictive values of vital sign based triage scores (REMS, MEWS and VIEWS Scores) regarding hospitalization, ICU admission and in-hospital mortality for geriatric patients presenting to ED

11. DESIGN

Prospective multicentre observational study.

12. DISEASES OF INTEREST

Non applicable.

13. OUTCOME VARIABLE

Length of stay in the ED and Length of stay in the hospital if hospitalized.

Status at 30 days: alive or dead.

14. STUDY POPULATION AND SAMPLE SIZE

Patients ≥ 65 years of age those presented to EDs with any symptom

Sample is generated with consecutive patients attending to EDs during study period.

15. STUDY PERIOD

From 19th October 2020 to 16th November 2020, seven consecutive days of recruitment.

2. GENERAL INFORMATION

A.Study Identification

1. Study Code EuSEM …….

Title: The European Geriatric Emergency Departments Registry Study (EGERS Study).

B. Study Design

Observational study

C. Study final products

Non applicable.

D. Promoter

European Society of Emergency Medicine(EuSEM).
The EuSEM office is located at:
Antwerpsesteenweg 124 B27
B-2630 Aartselaar, Brussels
Belgium

E. Biological samples responsible

Non applicable.

F. Study monitors

Non applicable.

G. Researchers and Centers (recruitment still ongoing)

For countries represented in the EUSEM Research network, the country PI is the country Lead of the RN.

3. INTRODUCTION, HYPOTHESIS AND OBJECTIVES

3.1 Background

Due to improved prevention, diagnosis and treatment modalities, life expectancy worldwide has risen. The number of adults over 65 years of age who are presenting to emergency services is increasing in parallel with the prolongation of the average life expectancy (1). While geriatric presentations to emergency services comprise 40–50% of all emergency service presentations in the U.S., it has been reported that 3–23% of all emergency service presentations from various regions of the country comprise patients of 65 years of age and older (2–4). There are specific management practices for patients who are 65 years and older at emergency services due to the presence of co-morbidities and the change of physiological responses to acute diseases in advanced age (1,2).

Several risk-scoring systems have been developed to define the severity class of the patient during their initial evaluation at emergency services and generally named as Early Warning Scores (5–6). Early Warning Scores (EWS) incorporate physiological measurements, which do predict outcome although the addition of other simple clinical parameters might further improve the sensitivity and specificity of these scores (7). On the other hand all these EWS are simple and easy to calculate, making their use appropriate in an emergency setting (7). Of these EWS, the Modified Early Warning Score (MEWS), and the Rapid Emergency Medicine Score (REMS) have been widely used for many years (8) and The Vital PAC Early Warning Score (VIEWS) score was recently developed for the same purpose (9, 10).

Only a few studies in the literature have evaluated risk-scoring systems for the geriatric patient group. Several studies have reported that risk-scoring systems, such as Identification of Seniors at Risk (ISAR) and Triage Risk Screening Tool (TRST), which are specifically developed for geriatric patients over 65 years who present to emergency services, are not sufficiently effective for evaluating

patients in more severe conditions (11,12). Other studies have reported that the ESI triage classification predicts the prognosis correctly in only half of the patients over 65 years of age (7,13). In another study that evaluated the MEWS for the geriatric patient group, which was calculated during the presentation in emergency services, has been stated to have a prognostic value in terms of a poor result (14).

Previously the TEDGeS (Turkish Emergency Departments Geriatric Scoring Study) pilot study was carried out and published (15,16). This study enrolled all geriatric patients (age ≥ 65 years) and carried out in 13 centers (University Hospitals, Government Education and Research Hospitals and Military Hospital ED) from different cities of Turkey.

Key findings were:

- Overall 30 % of hospitalized patients from ED are elderly patients and 30 % of these hospitalized patients were ICU hospitalizations
- In hospital mortality rate is about 6 % which is very high for general hospitalized patients
- The most common presenting symptoms are related to gastrointestinal systems and about 80 % of the cases using at least one chronic medication (22.2 % of the cases using more than 4 chronic medications
- About 45 % of the cases final diagnosis are related to cardiovascular system and gastrointestinal system and nearly 85 % of the hospitalized cases are treated in non-surgical clinics (cardiology-pulmonology-internal medicine 65 %)
- MEWS, VIEWS and REMS scores are significantly high in hospitalized patients compared to discharged from ED and also these three scores are high in ICU hospitalized patients compared to both ward hospitalized and discharged patients.

- MEWS, VIEWS and REMS scores are significantly high in non-survivors compared to survivors.
- MEWS, VIEWS scores has higher sensitivity and specificity in terms of in-hospital mortality

These results suggest that geriatric patients not only constitute significant proportion of ED presentations but also they need more hospitalization. The predictive powers of the MEWS, VIEWS and REMS scores for hospitalization and mortality in geriatric patients those presented to ED are significantly high and might be concerned in the ED triage of these patients.

References

1. Pines JM, Mullins PM, Cooper JK, Feng LB, Roth KE. National trends in emergency department use, care patterns, and quality of care of older adults in the United States. J Am Geriatr Soc 2013;61:12-7.
2. Roberts DC, McKay MP, Shaffer A. Increasing rates of emergency department visits for elderly patients in the United States, 1993 to 2003. Ann Emerg Med 2008;51:769-74.
3. Baz U, Satar S, Kozaci N, Acikalin A, Gulen M, Karakurt U. Geriatric patient admissions to emergency service. JAEM 2013, in press
4. Kekec Z, Koc F, Buyuk S. Review of geriatric patients hospitalization in emergency department. JAEM 2009;8(3):21-4.

5. Platts-Mills TF, Travers D, Biese K, et al. Accuracy of the Emergency Severity Index triage instrument for identifying elder emergency department patients receiving an immediate life-saving intervention. Acad Emerg Med 2010;17:238-43.
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3.2. Study objectives

MAIN OBJETIVE

The main objective of this project will be

- To determine Epidemiologic and Age Related Characteristics of Geriatric Patients presenting to the ED across Europe.

SECONDARY OBJETIVES

- To evaluate Early Warning Scoring systems (REMS, MEWS and VIEWS Scores) and determine most suitable Geriatric Emergency Medicine Risk Score regarding hospitalization, ICU admission and in-hospital mortality for patients
- To determine the most effective triage elements that can be used to predict hospitalization of geriatric patients presented to ED

- To determine the in hospital mortality and short term mortality rates of the patients above 65 years of age presenting to the ED across Europe.
- Sub analysis of ED discharged patients versus admitted patients for characteristics, comparison to recommended care and re-ED visit.
- Comparison of European data characteristics, investigation, treatment and outcome to similar data in other part of the world.

4. STUDY DESIGN

4.1. Study Design

Prospective non interventional cohort study in European EDs.

5. SELECTION OF CASES

5.1. Setting

Hospital Emergency Departments

5.2. Population Selected

Patients ≥ 65 years of age those presented to EDs with any symptom

5.3. Inclusion criteria

- ✓ Consecutive geriatric patient presenting to the ED with any symptom
- ✓ 65 years or older

5.3. Exclusion criteria

- ✓ No acceptance to participated
- ✓ End of life patients

5.4. Variables included on the study

Variables are reflected on the Case Report Form

5.5. **Participation centres**

Sites recruitment is still ongoing.

5.6. Sample size

- ✓ All of the patients over 65 years who had presented to emergency services due to acute medical or surgical reasons during the 7 days study period are to be included. Patients younger than 65 years of age will be excluded from the study. The patients who had been brought to emergency services after having undergone cardio pulmonary resuscitation by the emergency medical team will be also excluded from the study.
- ✓ We strive for at least 25 patients per site per study period with a complete case report form (CRF). (This number is based on our pilot study, TEDGeS - Turkish Emergency Departments Geriatric Scoring Study)
- ✓ Each participating center will have to enroll all consecutive cases.

5.7 Study period

7 consecutive days from 8:00 AM to 8:00 AM

6. TREATMENT

No modification on the selected management is required.

7. STUDY METHODOLOGY. INSTRUMENTS AND PROCEDURES

7.1. Recruitment methodology.
Consecutive geriatric patient presenting to the ED during the selected study periods.

7.2. Instruments

Case report form (CRF): Appendix 1

8. ADVERS EVENTS

No intervention on establish management is requiring.
Adverse events registry and declaration is no applicable.

9. ETHICAL ASPÈCTS

9.1. Ethical committees

Evaluation and acceptance of the protocol by local Ethical Committees is mandatory for each participating site.

9.2. Inform consent

Depending the local regulation, an informed consent through a document might be needed.

9.3. Confidentiality

No personal data is included on the database and all the CRF forms will be filled with 'CASTOR EDC' Clinical Data Management System, which enables secure data processes. Each center and country PI will be given a password to enter the data into CRF which will be secured and only be opened with the specific password or study managers' password.

9.4. Good practices

Study should follow any local regulation related to good practices on medical research activities.

10. LOGISTIC ASPECTS

10.1. National Coordinator

There will be one national coordinator in each participating country.
His responsibilities are:

- ✓ Select the participation centers.
- ✓ To be a link between the sites and the European PIs
- ✓ Participate on the final analysis and report.

10.2. Case report form

Appendix 1

10.3. Protocol

10.3.1. Protocol modifications

Any change in the protocol has to be accepted by the EGERS steering committee and approved by the local ethics committee.

10.3.2. Changes in the protocol during the recruitment period

No changes are accepted

10.4. Data management

CRF are completed anonymously with 'CASTOR EDC' Clinical Data Management System, local researchers are responsible of quality in the information collected.

10.4.1. Data collection

Promoter will provide the necessary tools (CRF) and online web access to transfer data into digital application to facilitated control and management and analysis.

10.4.2. Data quality control

Specific indicators are establishing to evaluated quality of the information basically % of missing data for each variable and % on NA data on each variable.

10.4.3. Data

Data bases will be collected and keep under control by the EGERS steering committee. Minimum time before deleting information is five years.

10.5. Publications

Any publication has to refer to the original protocol and promoter EGERS EuSEM Research Network.
Any publication has to be communicated to National coordinators.
No use or transmission of data to a third party may be made without the prior consent of the EGERS Steering Committee
Each site will have access to its own data.
Each publication project must be submitted to the EGERS Steering Committee

10.6. Data property

Data control and property belong to the promoter: EuSEM

10.7. Author Ship

The EGERS Steering committee will be in charge of the coordination of all the articles that will be published.

The 1st author will be the one that writes the article

3 positions as authors will be dedicated to members of the EGERS Steering Committee

Position as author will also be dedicated to people who actually participated in the development of the protocol and in the drafting of the results and also the number of patients with a complete CRF.

11. ANALYSIS

11.1. Data Analysis

Patients will be classified based on their ages, emergency medicine diagnosis and early warning scores.

The normality analyses of the data will be performed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The data did not comply with normal distribution. The continuous variables will be expressed as the median (inter-quartile range), and the categorical variables were expressed as a number (percentage). The inter-group differences between the continuous variables will be evaluated using the Kruskal-Wallis test and the Mann-Whitney U test (with Bonferroni correction). The inter-group differences between the categorical variables will be evaluated using the Chi-square and Fischer Exact tests. The predictive power of the scores for hospitalization and mortality in hospital will be evaluated using the Receiver Operating Characteristic (ROC) analysis. The values of the Areas Under the ROC Curve (AUC) will be evaluated. The optimum cut-off points of the scores will be determined for both of the main endpoints using the Youden index (sensitivity+specificity-1).

Using these determined cut off points for the sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio (+) and likelihood ratio (-), the values of both the scores will be calculated for both hospitalization and mortality at the hospital. Graph representation will be used to increase understanding of data.

11.2. Missing data

Certain crucial variables are needed to accept a CRF as a useful one.

11.3.1. Sample size

As this is a descriptive study, a formal sample size calculation has not been performed.

Based on our past experience of similar studies, we would expect to enroll between 40 and 50 sites each with an average number of patients of at least 25/site per 7 days study period.

Appendix 1: Case Report Form

EGERS CRF

European Geriatric Emergency Departments Registry Study

Inclusion criteria: All consecutive patients aged 65 or older presenting to the Emergency

Proposed study period, 7 consecutive days from 19th October 2020 to 16th November 2020: …….. (period in which recruitment was performed)

First 3 Letters of the Country |__|__|__| Site |__|__| Patient N |__|__|__|

Day of admission: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Fiday ☐ Saturday ☐ Sunday

Time of admission: ☐ 00:00-08 00 ☐ 08:01-16 00 ☐ 16:01-20 00 ☐ 20:01-23 59

Gender: ☐ M ☐ F Age (yo) |__|__|__|

Major Presenting Complaint: (Just Check One Major Complaint)

Non-Traumatic Complaint

- ☐ **Abdominal Pain**
- ☐ **Agitation and Psychosis**
- ☐ **The Alcoholic Patient**
- ☐ **Back Pain**
- ☐ **Bleeding**
- ☐ **Chest Pain**
- ☐ **Dizziness (Vertigo)**
- ☐ **Extremity Pain and Numbness**
- ☐ **Fever (Elevated Temperature)**
- ☐ **Headache**
- ☐ **Hypotension**
- ☐ **Jaundice**
- ☐ **Mental Status Change and Coma**
- ☐ **Palpitations and Tachycardia**
- ☐ **Rash**
- ☐ **Seizure**
- ☐ **Shortness of Breath**
- ☐ **Syncope and Near-Syncope**
- ☐ **Toxic Ingestion**
- ☐ **Change in Vision**
- ☐ **Weakness and Fatigue**
- ☐ **Abnormal findings on examination of blood (Hyperglycemia, Anemia, etc)**
- ☐ **Other Non trauma……**
  ……
  ……

Traumatic Complaint

- ☐ **Falls**
- ☐ **Motor Vehicle Accidents**
- ☐ **Pedestrian Struck**
- ☐ **Burns**
- ☐ **Assaults**
- ☐ **Other Trauma……**
  ……
  ……
  ……
  ……

EGERS

Presentation Symptoms and Signs:

Systolic Blood Pressure: |__|__|__| mmHg

Diastolic Blood Pressure: |__|__|__| mmHg

Heart Rate: |__|__|__| bpm

Temperature: |__|__|.|__| ° C

Respiratory rate/min: |__|__|

Oxygen saturation (SpO2): |__|__|__| %

Needs additional oxygen supply with nasal cannula or face mask: O Yes O No

*Glasgow Coma Score: Eye:|__| Voice:|__| Motor: |__| **TOTAL:** |__||__|*

Co-morbidities:

- ☐ *Coronary artery disease*
- ☐ *Left Ventricular Failure*
- ☐ *Right Ventricular Failure*
- ☐ *Prior coronary revascularization (Bypass)*
- ☐ *Chronic Obst. Pulm. Disease*
- ☐ *Asthma*
- ☐ *Chronic renal disease wo routine dialysis*
- ☐ *Chronic renal disease with routine dialysis*
- ☐ *Prior stroke (Hemorrhagic or Ischemic)*
- ☐ *Diabetes mellitus*
- ☐ *Hypertension*
- ☐ *Dyslipidemia Chronic*
- ☐ *Liver disease*
- ☐ *Chronic inflammatory disease*
- ☐ *Active/recent malignant tumor*
- ☐ *Anemia*
- ☐ *Dementia, Alzheimer*
- ☐ *Immunosuppression/AIDS*
- ☐ *Alcohol (> 30g/day for M and > 20 g/day for F)*
- ☐ *Smoking (Active or stopped within last year)*
- ☐ *Other.....*
  .....

Chronic Medications:

- ☐ *Beta-blockers*
- ☐ *Calcium antagonists*
- ☐ *ACE Inhibitors or Angiotensin II receptor blockers*
- ☐ *Diuretics*
- ☐ *Statins*
- ☐ *Antiplatelet*
- ☐ *NSAID or Other Analgesics*
- ☐ *Inhaled Beta2mimetics*
- ☐ *Inhaled steroids*
- ☐ *Oxygen +/- NIV at home*
- ☐ *Oral Antidiabetics*
- ☐ *Insulin*
- ☐ *Oral Steroids*
- ☐ *Cardiac Glycosides*
- ☐ *Vit K antagonists*
- ☐ *Psychiatric treatment*
- ☐ *Antidepressant*
- ☐ *Antiepileptic*
- ☐ Chemotherapy Drugs
- ☐ *Other.....*
  .....

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Consequence of ED Presentation:

Final (Hospital or ED for discharged patients) Principal Diagnosis (only one diagnosis):
……
……

☐ *Patient Has Home Care Service*
O *Yes* ***O*** *No*

☐ *Patient Has History of Falls*
O *Yes* ***O*** *No*

☐ *Patient Has Temporary Disorientation*
O *Yes* ***O*** *No*

☐ *Discharged From the Emergency Department*
Length of stay in ED: |__|__|__| (hours)

☐ *Admission to the Emergency Observation unit*
Length of stay in Obser. Unit: |__|__|__| (hours)

☐ *Admitted to Wards*
O *Cardiology* ***O*** *Pneumology*
O *Internal Medicine* ***O*** *Geriatrics*
O *General Surgery* ***O*** *Neurosurgery*
O *Orthopedics/Traumatology*
O *Thorax Surgery* ***O*** *Cardiovascular Surgery*
O *Other ……..*

☐ *Admitted to Intensive Care Unit*

☐ *Death at ED*

☐ *Death during Hospitalization*

For HOSPİTALİZED PATİENTS
STATUS at 30 days:

30 days: ***O*** *Alive* ***O*** *Death*

If Admitted to Wards or ICU

☐ *Total Length of Stay in Hospital: |__|__| (days)*

☐ *Total Length of Stay in Wards: |__|__| (days)*

☐ *Total Length of Stay in ICU: |__|__| (days)*

☐ *Still in Wards*

☐ *Still in ICU*

Appendix 2

Country questionnaire

Number of ED proposed

Emergency Department Questionnaire

Institution:

Address:

Local PI:
Last name: First name:

Phone:

e-mail address:

How many patients per year do you receive in your Emergency Department (ED) _____

How many patients per year do you hospitalize either in you hospital or in another hospital: _____

Total number of patients presented to your ED during the study week _____

Population served (habitants) by your ED _____

Is your ED located in a: **(check ONLY ONE BOX)**
Teaching hospital: ☐ General hospital: ☐

How many full time medical staff members do you have in your ED: _____

How many full time nurse staff members do you have in your ED: _____

Do you have an observation unit in your ED? Yes ☐ No ☐

Are patients admitted to the ED observation unit considered as hospitalized? Yes ☐ No ☐

Who perform the triage: Nurse ☐ Physician ☐

COMMITMENT TO CONFIDENTIALITY OF DATA

Dr./ Hospital

It is noted:

• To be undertaken the study entitled: "EGERS (European Geriatric Emergency Departments Registry Study)." by reviewing data from medical records, under the trial approved by the ethical Committee of research clinic of the Hospital
• Who undertakes to keep strict confidentiality of personal data from the source.
• Test results may be reported in congresses, meetings and scientific publications always safeguarding the confidentiality of personal data.

Signature: Dr. ……
……
……
……
……

In COUNTRY , DATE

PARTICIPANT INFORMED CONSENT PAPER

Research Project Title: EGERS (European Geriatric Emergency Departments Registry Study)
Promoter: Dr./Dr.
I (name and surname of the patient or family member by specifying the degree)...
I have read the information sheet that it has given me.
I could do the study questions.
I have received sufficient information on the study.
I have spoken to: Dr/Dr. (name of the researcher)
I understand that my participation is voluntary.
I understand that I may withdraw my study:

1. Whenever
2. Without having to give explanations.
3. Without that this impact on my health care.

I freely provide my agreement to participate in the study.

SIGNATURE of participant: ……..

SIGNATURE of RESEARCHER Dr. ……..
……
……
……
……

DATE: ……

INFORMATION SHEET TO THE PATIENT

The Study Title: EGERS (European Geriatric Emergency Departments Registry Study)
Promoter: Main RESEARCHER Mehmet Akif KARAMERCAN MD PhD, Chair of the Geriatrics Special Interest Group of EuSEM Research Committee

INTRODUCTION
We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the Committee of ethics of the research of the Hospital….., according to the legislation in force, and is carried out with respect for the principles contained in the Helsinki Declaration and the standards of good clinical practice. Our intention is just that you are receiving the correct information and sufficient so that you can evaluate and judge whether you want to or not to participate in this study. So read this fact sheet with attention and we will clarify any doubts that might arise after the explanation.
In addition, you can consult with persons it deems appropriate.

VOLUNTARY PARTICIPATION: you should know that your participation in this study is voluntary and you can decide not to participate or change its decision and withdraw consent at any time, without therefore will alter the relationship with your doctor or causing prejudice in its treatment.

GENERAL DESCRIPTION OF THE STUDY:
The main objective of this project will be

- To determine Epidemiologic and Age Related Characteristics of Geriatric Patients presenting to the ED across Europe.

- To evaluate Early Warning Scoring systems and determine most suitable Geriatric Emergency Medicine Risk Score

DESIGN OF THE STUDY:
It is a prospective, observational, longitudinal, multicenter, multi-continental study. The estimated duration of study is three (3) months, will be carried out by the emergency room doctors of the emergency service of.... It does not involve risks for the patient.

Thanks to your cooperation in the present study, the population of the European Union, will benefit and therefore it may save lives, which would not be possible without their collaboration, and this study. There is no problem in the participation of women in fertile age. The treatment that will receive is not going to be changed by its involvement in the study. The doctor responsible for the study (Dr/Dra), can provide you more information, if desired.

Treatment, communication and the transfer of personal data of all participating subjects shall comply with provisions in the organic law ……..of protection of data of a personal nature, and its development regulations. According to the provisions of the above-mentioned legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which should be addressed to your physician study.

Data collected for the study will be identified by a code and only your doctor's study and collaborators can relate this data with you and your medical history. Therefore, your identity will not be disclosed to any other person.

COMPENSATION: your participation in the study does not imply you any expenses.

OTHER RELEVANT INFORMATION: if you decide to withdraw the consent to participate in this study, no new data will be added to the database, and it may require the destruction of all identifiable samples previously retained to prevent the implementation of new analysis, while those responsible for the study may continue to use information collected about you until then, unless you expressly object. If you is removed from the study, by some of the expressed reasons, your doctor will prescribe a treatment appropriate to his illness.
By signing the attached consent sheet, undertakes to comply with the procedures of the study explained him.

Dr.

In COUNTRY, DATE