SRH Wald-Klinikum Gera gGmbH, Lehrkrankenhaus der Friedrich-Schiller-Universität Jena, Postfach 1662, 07506 Gera

Zentrum für Innere Medizin -
Departement für Gastroenterologie, Hepatologie, Nephrologie und Allgemeine Innere Medizin

Chefarzt:
Prof. Dr. med. habil. U. Will

06/12/2015

DECLARATION ON THE TYPE OF RESEARCH AND REQUIREMENT OF AN IRB STATEMENT

In3 - Gr

World J Gastroenterol - Manuscript ID: 18640 (Will *et al.*)
"Endoscopic ultrasonography-guided drainage of the pancreatic duct (EUPD) after unsuccessful ERP in patients with symptomatic obstruction and enlargement of the pancreatic duct: indications, interventional technique and therapeutic results in a long-term single-center study

By this document, the authors declare that – as one of the members of the local Institutional Review Board (IRB) assessed – statement of and registration by the IRB for this type of research is not mandatory since, in particular, "**Endoscopic ultrasonography-guided drainage of the pancreatic duct (EUPD)"** was used in daily clinical practice as a – in the mean time - well established procedure in the reporting department.
Therefore, in our opinion, such additional statement of the ethic committee is not required as we asked our IRB in comparable situations a couple of times.
In detail, we registered only patient-associated data on the systematic use of "EUPD" under various circumstances and indications in daily clinical practice as pointed out in the manuscript but independently of the (interests of) patients.

Furthermore, as we stated above in general; the technique is clinically used in several endoscopic units throughout the country and the world with appropriate expertise according to its indication. Derived from this, there is – actually – no imponderable risk or side effect for the patient any more as it may become possible in the use of any medication.

In addition, our register with patient-associated data is led according to the requirements of the German "Landes- und Bundesdatenschutzgesetz" ("law on data safety"); then, data were evaluated anonymously without any possible inference to an individual patient.

Last but not least, data has been generated at a tertiary center and associated hospital to a University Medical School.
One of their basic tasks is (according to the "Hochschulmedizingesetz" ["law on academic medicine"]) to perform clinical research in addition to clinical care for patients.

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Chefarztsekretariat
Frau M. Große
Telefon: 0365 828 2401
Fax: 0365 828 2402
e-Mail: marion.grosse@wkg.srh.de

Station M11
Oberarzt
Dr. med. Gerlach
Gastroenterologie/
Hepatologie
Telefon: 0365 828 2110

Station M12
Oberarzt
Dr. med. Goldmann
Gastroenterologie/
Hepatologie
Telefon: 0365 828 2210

Station M14
Oberarzt
Dr. med. Graf
Nephrologie/
Allgemeine Innere Medizin
Telefon: 0365 828 2410

Endoskopie
Oberarzt
Dr. med. Wanzar
Telefon: 0365 828 6312

Ultraschall
Oberarzt
Dr. med. Graf
Telefon: 0365 828 2428

Medizinische Ambulanz
Schwester Elke
Telefon: 0365 828 2318

Sprechstunden
nach telefonischer Vereinbarung

- Chronische-entzündliche Darmerkrankungen
- Hepatologie
- Spezielle gastroenterologische Probleme
- Fachberatung Sonografie/Endoskopie
- Gastroenterologisches Interdisziplinäres Konsil
jeden Mittwoch 14:30 Uhr

And, if you are benevolent to the issue, leading such register of patient data can be considered closed to epidemiological studies, which do not need any statement of an ethic committee.

However, according to the "Allgemeinen Vertragsbedingungen" ("general regulations on contracts") of the local contract between physician and the patient, ("Arzt-Patienten-Vertrag") in its current version from 2006, article [§] 16, paragraph [Absatz] 4, it is not permitted to evaluate anonymous data.

Taken together, there is no remaining option that we cause any harm to the patient but, in contrast, our results can even be or become beneficial for the patient(s) if we achieve additional finding, insight and knowledge – as our main result of the study indicates (see sections "Abstract", "Results" and "Discussion").

In conclusion, if the Editor(-in-chief) decides to do so and favors it, we suggest to add a sentence at the end of the "Patients and Methods" section such as:
"Because of the well established clinical, in particular, use of EUPD in selected centers, as e.g. also indicated in a few studies published on the subject, statement of the ethic committee appeared not to be necessary according to the usual requirements in such or comparable circumstances."

Many thanks for your understanding,

F. Meyer (corresp. author, on behalf of the 1st author & the co-authors)
-F. Meyer-

Prof. Dr. med. habil. U. Will
Head, Dept. of Gastroenterology
(first author)