Latest Achievements

SORAMIC clinical trial on ASCO Annual Meeting in June 3-7 2011, Chicago, Illinois:

This year, the ASCO (American Society of Clinical Oncology) Scientific Committee received nearly 5,000 abstracts for review. It is with great pleasure that we announce that the SORAMIC abstract (Title: Evaluation of sorafenib in combination with local microtherapy guided by gadolinium-EOB-DTPA enhanced MRI in patients with inoperable hepatocellular carcinoma) was selected for poster presentation for the Trials in Progress Poster Session. The poster was presented by investigators from Magdeburg University Hospital.

Fifteen SORAMIC study sites now initiated, six sites recruiting:

With the initiation of two study sites in Warsaw (Poland) in May 2011 there are now 15 active study sites in SORAMIC. Further study sites that are open for recruitment are: Amsterdam (The Netherlands), Vienna (Austria), Magdeburg (Germany), Leuven (Belgium), Charité Berlin (Germany), Potsdam (Germany), Linz (Austria), Regensburg (Germany) Karlsruhe (Germany), MLK Berlin (Germany), Pamplona (Spain), Munich University Hospital (Germany) and Munich Hospital Bogenhausen (Germany).

Recruitment Status 2011-06-09:
By this date 25 patients have been included into SORAMIC study as follows:

| Screening Phase: | 2 patients |
| Local Ablation Treatment: | 5 patients |
| Palliative Treatment: | 10 patients |
| Screen Failures: | 7 patients |
| Early Terminated (pall. treatment): | 1 patient |

Recruiting sites:
University of Magdeburg (GER), Medical University Vienna (AU), Charité Medical University Berlin (GER), Hospital Ernst-von Bergmann, Potsdam (GER), University Hospital Leuven (B), University Hospital Pamplona (ESP), Hospital „Barmherzige Schwestern“ Linz (AU)

Follow up on the Recruitment Status on www.soramic.com!

For further information on this study please contact:

Magdeburg, 2011-06-09
SORAMIC Web Seminar for Study Coordinators - Webcast Link now on SORAMIC Website!

The first Web Seminar within SORAMIC has been designed for SORAMIC study coordinators and took place live as an online seminar on 12-04-2011. The Webcast of the seminar can be viewed on the SORAMIC website. In order to get a certificate please register first under the link given on the website and watch the complete webcast. You will then receive a certificate from the sponsor of the study. Please let us know any time if you have problems watching the webcast. Make sure you have an updated media player installed on your computer.

The link to the webcast start page: www.soramic.com/home/soramic-news/ (please klick on the link in the respective news item)

SORAMIC Sub-Studies:

SORAMIC is an open source project. So far 16 proposals for sub-studies have reached us to be included into SORAMIC. We would very much like to thank all contributors and also encourage other investigators to send us their contributions as well. For your information please find the list of the sub study titles we received and reviewed so far:

1. Surveillance of liver cirrhosis under Sorafenib or Placebo (with RFA) by MRI (local ablative group)
2. The value of Dyna-CT for HCC imaging in terms of lesion detection (palliative group)
3. Additional value of delayed phase dynamic MRI scans (120 versus 180 and 240 seconds) for the detection and characterization of HCC (local ablative group, follow-up only)
4. Outcome of local therapy of small HCC (<3cm) (local ablative group)
5. Early prediction of therapeutic response after treatment of advanced HCC Sorafenib alone by MRI (DWI/Perfusion) (palliative group)
6. Evaluation of transarterial occlusion of the gastroduodenal artery by standard pushable coils versus vascular plug: a study of SORAMIC, a prospective randomized multicenter trial on Sorafenib and microtherapy in HCC (palliative group)
7. Long-term follow-up of equivocal lesions between 5 and 20 mm in cirrhotic liver: Value of Gd-EOB-DTPA-enhanced MRI (local ablative group, follow-up only)
8. Additional value of delayed phase CT scans for the detection and characterization of HCC (local ablative and palliative group)
9. Evaluation of imaging findings after SIRT – value of DWI to identify responders early (palliative group)
10. Relationship between sorafenib plasma levels and treatment response within the SORAMIC study (local ablative and palliative group)
11. Early prediction of therapeutic response after RFA alone by MRI (local ablative group)
12. Prediction of liver toxicity and survival by pre therapeutic cytokine blood levels (local ablative and palliative group)
13. Expression profile of Dickkopf (Dkk) 2 and 4 – modulators of Wnt-related signaling
14. Validation of new molecular targets relevant in hepatocellular carcinogenesis the have been primarily identified by bioinformatic gene-expression network analysis
15. Urine biomarkers of HCC staging and prognosis: a proteomic approach (local ablative and palliative group)
16. Serum biomarkers of prognosis: VEGFs and PDGFs (local ablative and palliative group)

For further information on this study please contact:

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Portrait SORAMIC Study Team: Charité - Universitätmedizin Berlin

At the Charité – Universitätmedizin Berlin, our scientists and physicians engage in state-of-the-art research, patient care and education. More than half of the German Nobel Prize winners in medicine and physiology come from the Charité. The Charité also has an international reputation for excellence in training. It extends over three campuses with more than 100 clinics and institutes. In 2010, the Charité celebrated its 300-year anniversary.

The study team in Berlin consists of Gastroenterologists, Radiologists and physicians in Nuclear Medicine, which cooperate closely to implement the SORAMIC study optimal.

Studyteam Charité:

Radiology
PI: B. Gebauer
Studynurse: D. Busch

Gastroenterology
Investigator: E. Schott
Studynurses: D. Baier, A. Göbels

Nuclear medicine
Investigator: H. Bertram, R. Röttgen

Within every Newsletter we would like to present a study team or individual persons that are important for the conduct of SORAMIC. We, therefore, kindly ask for your support to provide us with information on your study team or individual persons for coming Newsletters.

For all SORAMIC related issues please contact: Ms. F. Sattler (phone: 0049 391 -67 1559, E-Mail: soramic@med.ovgu.de)