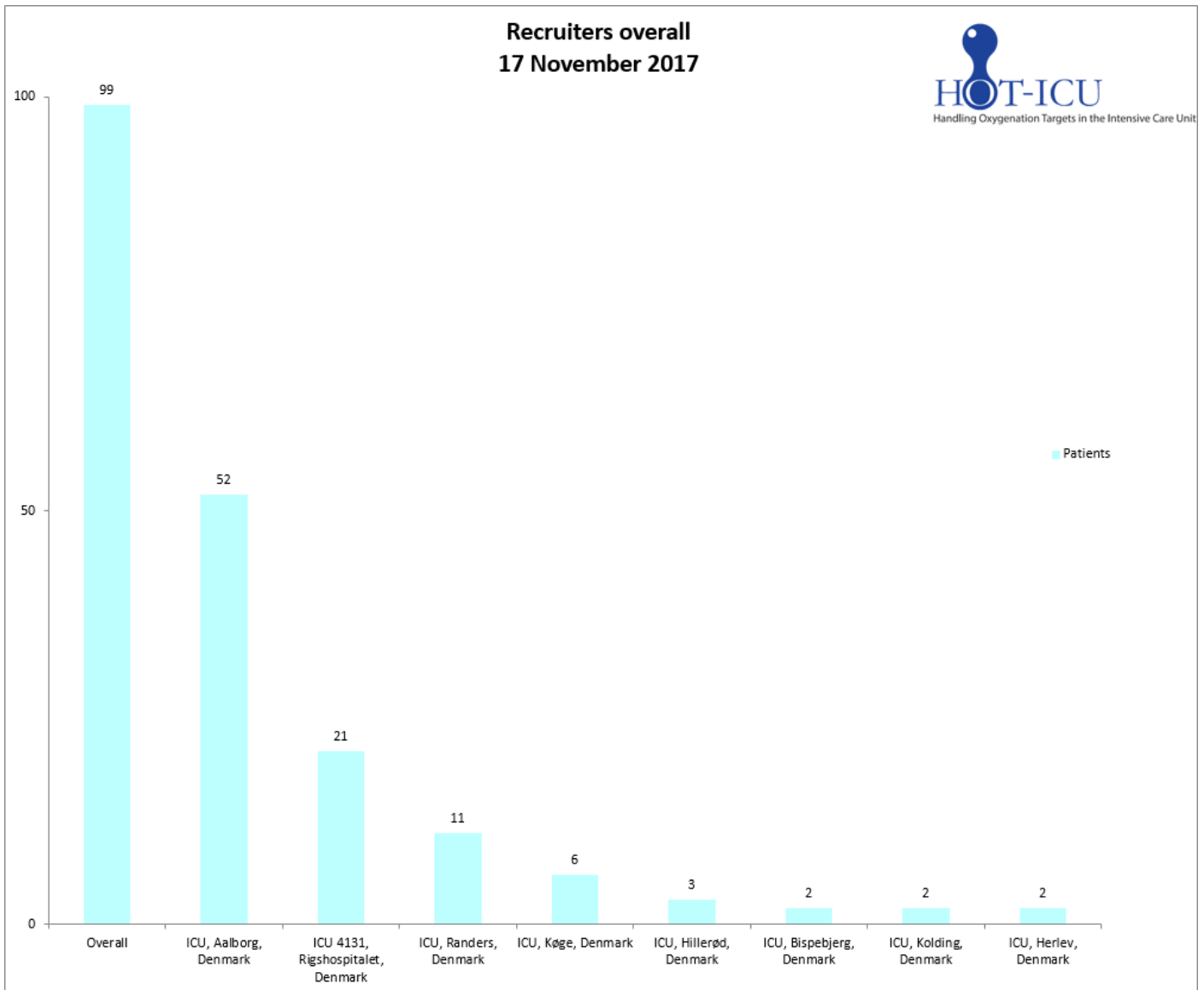




## Place in Site Master File #13f

HOT-ICU newsletter – November 2017

Thank you very much for your great engagement in the HOT-ICU trial.



### Status

During the last month, the ICUs at Køge, Hillerød, Kolding, Bispebjerg and Herlev has successfully joined the HOT-ICU trial. Welcome to you all.

We are actively recruiting at eight sites now and have randomised 99 patients in total. Within the next month, at least two additional Danish sites are expected to start inclusion.

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Relevant authorities in Switzerland and the Netherlands have approved the trial, and we are now preparing initiation of the trial at the primary sites in Basel and Groningen.

**A few things to highlight:**

1. Please check the site-master-file log (<http://www.cric.nu/hot-icu-log-for-site-master-file/>) regularly for updates. There has been several recent updates including:
  - The first amendment to the protocol due to a change of primary investigators at three Danish sites. The new protocol is available at <http://www.cric.nu/hot-icu-protocol-approved/>. As there has been no change of the scientific content within the protocol, the version number remains version 1.2. The relevant protocol pages 11 and 12, listing the Danish site investigators should be printed and placed in the physical site master file as an amendment
  - A standard operating procedure (SOP) for the Danish procedure of reporting suspected unexpected serious adverse reactions (SUSARs) is now available at <http://www.cric.nu/hot-icu-standard-operating-procedure-for-susar-reporting/>
2. We are experiencing a significant amount of protocol violations, please ensure that the specific notifications of “major protocol violations” are handled to secure adherence to the protocol
3. Please remember to screen all patients fulfilling the inclusion criteria within 12 hours from ICU admission
4. Inclusion of patients, recruiting HOT-ICU trial sites, top recruiters etc. are updated at least twice weekly at [www.cric.nu/hot-icu](http://www.cric.nu/hot-icu)

If you have any questions, do not hesitate to send an e-mail to [hot-icu@cric.nu](mailto:hot-icu@cric.nu) or to contact the HOT-ICU hotline (+45 2118 2543). Please **leave a message and your phone number if the call is not answered** and we will call you back as soon as possible.

Please archive this newsletter in your site master file.

The next newsletter will be due medio December 2017.

**Best regards,**

**Bodil and Olav**