

Amendments

To study protocol

Oral appliance for the treatment of obstructive sleep apnoea: A randomized controlled blinded multicentre study comparing the effect of two devices

Change #	Date	
1.	2014-03-01	GI decides not to include a sleep diary in the study.
2.	2014-03-01	The questionnaire variable "Rating of how important the appliance is for the subject / partner" is not included in the final CRF. The variable is then excluded.
3.	2014-06-01	Consultation GI, EN and AF – decides to unblind the intervention when the patient has passed the evaluation visit i.e. the study is open labelled following the evaluation 9 weeks after baseline.
4.	2014-11-20	Investigators meeting when a decision is taken to include also a polygraphic examination at the 1-year follow-up
5.	2015-05-15	GI decides to open one additional center – Malmö University, department of Orofacial pain and jaw function, accountable TL
6.	2015-05-28	Supplementary ethical application submitted to Ethics Committee in Uppsala
7.	2015-06-04	Supplementary ethical application approved

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