

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Timing Of Primary Surgery for cleft palate (TOPS): Protocol for a randomised trial of palate surgery at 6 months versus 12 months of age
AUTHORS	Shaw, William; Semb, Gunvor; Lohmander, Anette; Persson, Christina; Willadsen, Elisabeth; Clayton-Smith, Jill; Trindade, Inge; Munro, Kevin; Gamble, Carrol; Harman, Nicola; Conroy, Elizabeth; Weichart, Dieter; Williamson, Paula

VERSION 1 - REVIEW

REVIEWER	Nivaldo Alonso University of São Paulo Brazil
REVIEW RETURNED	08-Mar-2019

GENERAL COMMENTS	Very well designed and cover aspects. Meticulous and very well written. The subject is very important could provide protocol definition for the remain question on palate surgery
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REVIEWER	Joseph Hardwicke Consultant Plastic Surgeon and Associate Clinical Professor, University Hospitals of Coventry and Warwickshire NHS Trust and University of Warwick Medical School, Coventry, UK
REVIEW RETURNED	08-Mar-2019

GENERAL COMMENTS	A timely and valuable study
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REVIEWER	Eleftherios Kaklamanos Hamdan Bin Mohammed College of Dental Medicine Mohammed Bin Rashid University of Medicine and Health Sciences Dubai, United Arab Emirates
REVIEW RETURNED	19-Apr-2019

GENERAL COMMENTS	I would like to thank the BMJ Open for the invitation to review this protocol and congratulate the Authors for their hard work on this very important subject. I would like to ask them why the chose perceived insufficient velopharyngeal function as the primary outcome, over others, such as speech.
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REVIEWER	Philip Kuo-Ting Chen Craniofacial Center Taipei Medical University Hospital Taipei Medical University Taipei, taiwan
REVIEW RETURNED	27-Apr-2019

GENERAL COMMENTS	This is a well designed prospective study. The study design is a model for this kind of study and should be published.
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VERSION 1 – AUTHOR RESPONSE

The authors response to the reviewers' comments are as follows:

Reviewer: 1

Reviewer Name: Nivaldo Alonso

Institution and Country: University of São Paulo Brazil

Please state any competing interests or state 'None declared': none

Please leave your comments for the authors below

Very well designed and cover aspects. Meticulous and very well written.

The subject is very important could provide protocol definition for the remain question on palate surgery

Authors' response: Thank you for your valuable comment.

Reviewer: 2

Reviewer Name: Joseph Hardwicke

Institution and Country: Consultant Plastic Surgeon and Associate Clinical Professor, University Hospitals of Coventry and Warwickshire NHS Trust and University of Warwick Medical School, Coventry, UK

Please state any competing interests or state 'None declared': non declared

Please leave your comments for the authors below

A timely and valuable study

Authors' response: Thank you for your valuable comment.

Reviewer: 3

Reviewer Name: Eleftherios Kaklamanos

Institution and Country: Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

I would like to thank the BMJ Open for the invitation to review this protocol and congratulate the Authors for their hard work on this very important subject. I would like to ask them why they chose perceived insufficient velopharyngeal function as the primary outcome, over others, such as speech.

Authors' response: Thank you for your comment. The manuscript has been revised and the authors have provided a clarification to on their choice of outcome measure.

The authors' would like to explain that adequate velopharyngeal function is a prerequisite for normal speech production. In children born with cleft palate, speech outcomes are often reported for velopharyngeal function and articulation. In the presence of insufficient velopharyngeal function, speech will inevitably be affected by symptoms such as hypernasality and nasal air emission to different degrees. In children with isolated cleft palate, articulation disorders occur less frequently than in children with complete cleft lip and palate. Insufficient perceived velopharyngeal function was therefore chosen to be the primary outcome and articulation outcomes as secondary outcomes.

Reviewer: 4

Reviewer Name: Philip Kuo-Ting Chen

Institution and Country: Craniofacial Center, Taipei Medical University Hospital, Taipei Medical University, Taipei, taiwan

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This is a well designed prospective study. The study design is a model for this kind of study and should be published.

Authors' response: Thank you for your valuable comment.