UNIVERSITY^{OF} BIRMINGHAM University of Birmingham Research at Birmingham

Clinical Methods and Design for a Phase II Randomised Control Trial to Assess the Efficacy and Safety of an 11β-Hydroxysteroid Dehydrogenase Type 1 Inhibitor (AZD4017) in Idiopathic Intracranial Hypertension: IIH:DT

Markey, Keira; Ottridge, Ryan; Mitchell, James; Rick, Caroline; Woolley, Rebecca; Ives, Natalie; Nightingale, Peter; Sinclair, Alexandra

DOI: 10.2196/resprot.7806

License: Creative Commons: Attribution (CC BY)

Document Version Peer reviewed version

Citation for published version (Harvard):

Markey, K, Öttridge, R, Mitchell, J, Rick, C, Woolley, R, Ives, N, Nightingale, P & Sinclair, A 2017, 'Clinical Methods and Design for a Phase II Randomised Control Trial to Assess the Efficacy and Safety of an 11β-Hydroxysteroid Dehydrogenase Type 1 Inhibitor (AZD4017) in Idiopathic Intracranial Hypertension: IIH:DT', *JMIR Research Protocols*, vol. 6, no. 9, e181. https://doi.org/10.2196/resprot.7806

Link to publication on Research at Birmingham portal

Publisher Rights Statement:

Markey KA, Mitchell J, Ottridge R, Rick C, Wooley R, Ives N, Nightingale P, Sinclair A Clinical Methods and Design for a Phase II Randomised Control Trial to Assess the Efficacy and Safety of an 11β-Hydroxysteroid Dehydrogenase Type 1 Inhibitor (AZD4017) in Idiopathic Intracranial Hypertension: IIH:DT JMIR Res Protoc 0000;##(##):e## URL: http://www.researchprotocols.org/0000/0/e0/ doi:10.2196/resprot.7806

General rights

Unless a licence is specified above, all rights (including copyright and moral rights) in this document are retained by the authors and/or the copyright holders. The express permission of the copyright holder must be obtained for any use of this material other than for purposes permitted by law.

•Users may freely distribute the URL that is used to identify this publication.

•Users may download and/or print one copy of the publication from the University of Birmingham research portal for the purpose of private study or non-commercial research.

•User may use extracts from the document in line with the concept of 'fair dealing' under the Copyright, Designs and Patents Act 1988 (?) •Users may not further distribute the material nor use it for the purposes of commercial gain.

Where a licence is displayed above, please note the terms and conditions of the licence govern your use of this document.

When citing, please reference the published version.

Take down policy

While the University of Birmingham exercises care and attention in making items available there are rare occasions when an item has been uploaded in error or has been deemed to be commercially or otherwise sensitive.

If you believe that this is the case for this document, please contact UBIRA@lists.bham.ac.uk providing details and we will remove access to the work immediately and investigate.

Protocol

Clinical Methods and Design for a Phase II Randomised Control Trial to Assess the Efficacy and Safety of an 11β-Hydroxysteroid Dehydrogenase Type 1 Inhibitor (AZD4017) in Idiopathic Intracranial Hypertension: IIH:DT

Keira Annie Markey^{1,2}, MRCP; James Mitchell^{1,2}, MRCP; Ryan Ottridge³, MPhil; Caroline Rick³, PhD; Rebecca Wooley³, MSc; Natalie Ives³, MSc; Peter Nightingale⁴, PhD; Alexandra Sinclair^{1,2}, PhD

¹Neurometabolism, Institute of Metabolism and Systems Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, United Kingdom

²Department of Neurology, Queen Elizabeth Hospital, Birmingham, United Kingdom

³Birmingham Clinical Trials Unit, Birmingham University, Birmingham, United Kingdom

⁴Institute of Translational Medicine, Queen Elizabeth Hospital, Birmingham, United Kingdom

Corresponding Author:

Alexandra Sinclair, PhD Neurometabolism, Institute of Metabolism and Systems Research College of Medical and Dental Sciences University of Birmingham The Medical School Edgbaston Birmingham, B15 2TT United Kingdom Phone: 44 1214158708 Fax: Email: <u>a.b.sinclair@bham.ac.uk</u>

Abstract

See manuscript file.

(JMIR Res Protoc 0000;##(##):e##) doi:10.2196/resprot.7806

KEYWORDS

11beta-HSD1; Randomised controlled trial; clinical protocol; Idiopathic Intracranial Hypertension; Clinical Trials, Phase II

Acknowledgments

See manuscript file.

Conflicts of Interest

See manuscript file.

Authors' Contributions

See manuscript file.



JMIR RESEARCH PROTOCOLS

Edited by G Eysenbach; ###Reviewer names will be inserted here### published 00 <u>Please cite as:</u> Markey KA, Mitchell J, Ottridge R, Rick C, Wooley R, Ives N, Nightingale P, Sinclair A Clinical Methods and Design for a Phase II Randomised Control Trial to Assess the Efficacy and Safety of an 11β-Hydroxysteroid Dehydrogenase Type 1 Inhibitor (AZD4017) in Idiopathic Intracranial Hypertension: IIH:DT JMIR Res Protoc 0000; ##(##):e## URL: http://www.researchprotocols.org/0000/0/e0/ doi:10.2196/resprot.7806 PMID:

©Keira Annie Markey, James Mitchell, Ryan Ottridge, Caroline Rick, Rebecca Wooley, Natalie Ives, Peter Nightingale, Alexandra Sinclair. Originally published in JMIR Research Protocols (http://www.researchprotocols.org), 00.00.0000. This is an open-access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Research Protocols, is properly cited. The complete bibliographic information, a link to the original publication on http://www.researchprotocols.org, as well as this copyright and license information must be included.

