

Clinical trial guideline committee

Sept 2025 update

Gisela Terwindt



International
Headache Society

Clinical trial guideline committee

Chair: Gisela Terwindt

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Peter Goadsby
Elizabeth Leroux
Richard Lipton
Patricia Pozo-Rosich
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Gloria Vaghi (Italy)

Guidelines of the International Headache Society for controlled trials of preventive treatment of chronic migraine in adults

Cephalalgia
2018, Vol. 38(5) 815–832
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Previous deliverables

Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth edition

Cephalalgia
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Guidelines of the International Headache Society for controlled trials of preventive treatment of migraine attacks in episodic migraine in adults

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David W Dodick⁴, Stephan D Silberstein⁵ , Richard B Lipton⁶,
Messoud Ashina⁷, Werner J Becker^{8,9}, Michel D Ferrari¹⁰,
Peter J Goadsby¹¹ , Patricia Pozo-Rosich¹²,
Shuu-Jiun Wang^{13,14} , Timothy T Houle¹⁵,
Thomas C van den Hoek¹⁶, Daniele Martinelli^{2,3}  and
Gisela M Terwindt¹⁰;
on behalf of the International Headache Society
Clinical Trials Committee

Guidelines of the International Headache Society for controlled trials of preventive treatment of migraine in children and adolescents 1st edition

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Ishaq Abu-Arafeh^{1,*}, Andrew D Hershey^{2,*},
Hans-Christoph Diener³ and Cristina Tassorelli^{4,5} ;
on behalf of the Clinical Trials Standing Committee
and the Child and Adolescent Standing Committee
of the International Headache Society

Previous deliverables by junior members

Adherence to the 2008 IHS guidelines for controlled trials of drugs for the preventive treatment of chronic migraine in adults

Marie Deen^{1,*} , Daniele Martinelli^{2,3,*} , Judith Pijpers⁴, Hans-Christoph Diener⁵, Stephen Silberstein⁶, Michel D Ferrari⁴, Messoud Ashina¹, Cristina Tassorelli^{2,3}  and Hsiangkuo Yuan⁶

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Have the IHS Guidelines for controlled trials of acute treatment of migraine attacks been followed? Laying the ground for the 4th edition

Alicia Alpuente^{1,2} , Cristina Tassorelli^{3,4} , Hans-Christoph Diener⁵, Stephen D Silberstein⁶  and Patricia Pozo-Rosich^{1,2}

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2021-2023 deliverables

Guidelines

Guidelines of the International Headache Society for clinical trials with **neuromodulation devices** for the treatment of migraine

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2021, Vol. 41(11-12) 1135-1151
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Cristina Tassorelli^{1,2*} , Hans-Christoph Diener^{3,*} ,
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Peter J Goadsby^{6,7} , Rigmor H Jensen⁸, Delphine Magis⁹ ,
Patricia Pozo-Rosich¹⁰, Hsiangkuo Yuan⁴,
Daniele Martinelli^{1,2} , Thomas van den Hoek¹¹,
Marie Deen⁸ , Messoud Ashina⁸ and Gisela M Terwindt¹¹

Guidelines

Guidelines of the International Headache Society for Clinic-Based Headache Registries, 1st edition

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Todd J Schwedt¹, Cristina Tassorelli^{2,3} ,
Stephen D Silberstein⁴ , Christina L Szperka⁵ ,
Tobias Kurth⁶ , Patricia Pozo-Rosich⁷,
Faisal Mohammad Amin^{8,9}, Richard B Lipton¹⁰,
David W Dodick¹, Messoud Ashina⁸,
Hans-Christoph Diener¹¹  and Gisela M Terwindt¹²

Original Article

Health technology assessment for the acute and preventive treatment of migraine: A position statement of the International Headache Society

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Isabelle Durand-Zaleski^{3,4}, Tobias Kurth⁵ ,
Michel Lantéri-Minet⁶, Richard B Lipton⁷,
Daniel A Ollendorf⁸ , Patricia Pozo-Rosich^{9,10},
Cristina Tassorelli^{11,12}  and Gisela Terwindt¹³

Guidelines

Guidelines of the International Headache Society for Controlled Clinical Trials in **Cluster Headache**

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Chin-Sang Chung⁵, Hans-Christoph Diener⁶ ,
David W Dodick⁷, Denys Fontaine⁸, Peter J Goadsby⁴ ,
Manjit Singh Matharu⁹ , Arne May¹⁰ , James S McGinley¹¹,
Stewart J Tepper¹², Rigmor Højland Jensen², Michel D Ferrari³,
for the IHS Standing Committee for Clinical Trials

IHS cluster headache trial guideline subcommittee

Chairs: Jean Schoenen, Rigmor Jensen and Michel D Ferrari
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Publications 2024 :

Guidelines

Guidelines of the International Headache Society for Controlled Clinical Trials in Idiopathic Intracranial Hypertension

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Alex J. Sinclair^{2,21}, Gisela M. Terwindt²² and Rigmor H. Jensen²³

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Guidelines



Guidelines of the International Headache Society for controlled trials of pharmacological preventive treatment for persistent post-traumatic headache attributed to mild traumatic brain injury

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Richard B. Lipton ^{10,11}, Patricia Pozo-Rosich ^{12,13}, Alexandra J. Sinclair¹⁴, Catherine D.
Chong ¹⁵, Alan G. Finkel¹⁶, Messoud Ashina^{3,5}, Todd J. Schwedt¹⁵, David W. Dodick^{5,15}, and
Gisela M. Terwindt¹⁷

Message of RWD guideline

Guidelines of the International Headache Society for Real World Data studies in headache.

Importance:

1. Real-world evidence (RWE) studies are an important tool for investigating the effectiveness in clinical practice and safety of treatments for headache disorders.
2. These studies use data that is generated from routine clinical practice from a variety of sources and can help to identify unmet needs in headache care and guide new therapies.
3. Real-world evidence (RWE) pertains to the clinical evidence surrounding the utilization, as well as the potential advantages or drawbacks of treatment, which is extracted through an analysis of real-world data (RWD).
4. RWE studies can present unique challenges, including data quality issues, selection bias, and confounding factors.

Publication in 2025 :



Guidelines

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Guidelines of the International Headache Society for Real-World Evidence studies in migraine and cluster headache

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Peter J. Goadsby^{6,7} , Messoud Ashina^{8,9} , Shuu-Jiun Wang^{10,11,12} ,
Hans-Christoph Diener¹³ , Cristina Tassorelli^{4,5} , and
Gisela M. Terwindt³

Discussion from last Round Table:

SUGGESTIONS FOR NEW CLINICAL TRIAL GUIDELINES:

1. **Menstrual Migraine:**

With increasing knowledge on menstrual migraine definition and increasing interest in the field it seems opportune to develop a specific “situational prevention” guideline

2. **Digital Therapeutics for Headache Management:**

With the increasing use of mobile apps and wearables for health management, clinical trials could evaluate the efficacy of digital tools based on ICHD-3 criteria for diagnosing, monitoring, and treating headache disorders.

3. **Combination Therapies:**

Explore guidelines for trials testing combined pharmacological and behavioral therapies, particularly in refractory headache disorders.

4. **Non-Invasive Neuromodulation:**

Given the rise in neuromodulation devices, new trials focusing on these technologies for different headache subtypes might be developed.

From this Round Table discussion:

SUGGESTIONS FOR NEW GUIDELINES :

1. **Menstrual Migraine:**

Should fit with current trials – need to engage EMA and FDA

2. **Digital Therapeutics for Headache Management:**

Can be explored further, also adding combination of pharmacological and behavioral therapies

3. **Combination Therapies:**

General remark, very difficult for pharmacological studies, mostly concerning side-effects and not the additional effect perse (remark Pfizer)

4. **Cluster headache:**

Need for other outcome measurements ?, suggestion to make a short amendment to the current guideline