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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality

Scientific Information Request on Strategies to Treat and Manage Infantile Hemangioma

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Strategies to Treat and Manage Infantile Hemangioma, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list to upload your documents.
E-mail submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address:
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
3710 SW U.S. Veterans Hospital Road
Mail Code: R&D 71
Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 58653 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Strategies to Treat and Manage Infantile Hemangioma.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Strategies to Treat and Manage Infantile Hemangioma, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2016.

This notice is to notify the public that the EPC Program would find the following information on Strategies to Treat and Manage Infantile Hemangioma helpful:

• A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.

• For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

• A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

• Description of whether the above studies constitute all ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a

voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2016.

The Key Questions

Our Contextual Questions (CQs) are as follows:

CQ1
What is known about the natural history of infantile hemangiomas, by hemangioma site and subtype? What are the adverse outcomes of untreated infantile hemangiomas? What characteristics of the hemangioma (e.g., subtype, size, location, number of lesions) indicate risk of significant medical complications that would prompt immediate medical or surgical intervention?

CQ2
What is the evidence that five or more cutaneous hemangiomas are associated with an increased risk of occult hemangiomas?

Our Key Questions (KQs) are as follows:

KQ1
Among newborns, infants, and children up to 18 years of age with known or suspected infantile hemangiomas, what is the comparative effectiveness (benefits/harms) of various imaging modalities for identifying and characterizing hemangiomas?

- Does the comparative effectiveness differ by location and subtype of the hemangioma?

KQ2
Among newborns, infants, and children up to 18 years of age with infantile hemangiomas who have been referred for pharmacologic intervention, what is the comparative effectiveness (benefits/harms) of corticosteroids or beta-blockers?

KQ3
Among newborns, infants, and children up to 18 years of age with infantile hemangiomas for whom treatment with corticosteroids or beta-blockers is unsuccessful what is the comparative effectiveness of second line therapies including immunomodulators and angiotensin-converting enzyme inhibitors?

KQ4
Among newborns, infants, and children up to 18 years of age with infantile hemangiomas who have been referred for surgical intervention, what is the comparative effectiveness (benefits/harms) of various types of surgical interventions (including laser and resection)?

PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting)

KQ 1

Population
Newborns, infants, and children up to 18 years of age with known or suspected infantile hemangiomas

Intervention(s)

Diagnostic imaging:

- Magnetic resonance imaging
- Computed tomography
- Magnetic resonance angiography
- Echocardiography
- Ultrasonography
- Endoscopy

Comparator

- Other workup evaluation approaches for treatment planning
- Other imaging modalities

Outcomes
- Ability to identify presence, number, and extent of hemangiomas and associated structural anomalies (sensitivity and specificity)
- Harms including, but not limited to, effects of sedation or imaging dye

Timing

- Immediate and short-term (ó 3 months)
- Long-term (> 3 months)

Setting
Inpatient and outpatient settings (e.g., pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

KQs 2, 3, and 4

Population
Newborns, infants, and children up to 18 years of age with infantile hemangiomas

Intervention(s)

KQ2 Pharmacologic interventions

- Systemic (e.g., propranolol) or topical (e.g., timolol) beta-blockers
- Corticosteroids (topical, intralesional, or systemic)

KQ3 Pharmacologic interventions

- Innmunosuppressants (e.g., sirolimus)
- Immunomodulators (e.g., imiquimod, interferon)
- Antineoplastics (e.g., intralesional bleomycin, intravenous vincristine)
- Angiotensin-converting enzyme inhibitors
- Antiangiogenic agents

KQ4 Surgical interventions

Laser treatment

- Pulsed dye
- Fractionated laser
- Argon
- Carbon dioxide
- Neodymium (Nd): Yttrium Aluminium Garnet YAG
- Erbium

Surgical treatment
- Cryotherapy
- Resection
- Embolization
- Radiofrequency ablation therapy

Comparator

KQ2, 3
- No treatment
- Other pharmacologic interventions
- Observation
- Complementary and alternative medicine (CAM) (e.g., massage, compression therapy, essential oils)

KQ4

- No treatment
- Other laser or surgical interventions
- Observation
- CAM (e.g., massage, compression therapy, essential oils)

Outcomes

Intermediate outcomes (KQ2, 3, 4)

- Size / volume of hemangioma
- Impact on vision
- Aesthetic appearance as assessed by clinician or parent

- Degree of ulceration
- Harms
- Quality of life

Final outcomes (KQ2, 3, 4)

- Marked improvement of hemangiomas
- Prevention of disfigurement
- Resolution of airway obstruction
- Preservation of vision
- Preservation of organ function (e.g., thyroid function, cardiac function)
- Resolution of ulceration
- Psychological impact on the patient
- Harms including: pain, bleeding, sequelae of scarring, skin atrophy, venous prominence, disfigurement, distortion of anatomic landmarks, ulceration, infection, hypopigmentation

Timing

KQ2, 3

- Immediate and short-term (ó 2 years of age)
- Long-term (> 2 years of age)

KQ4
- Immediate and short-term (ó 3 months)
- Long-term (> 3 months)

Setting
Inpatient and outpatient settings (e.g., pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

Dated: December 30, 2014.

Richard Kronick,
AHRQ Director.

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