File No. M-11019/5/2026-CG
Government of India
Ministry of Health & Family Welfare

PUBLIC NOTICE

Subject: Awareness about Autism Spectrum Disorder (ASD) for patients/caregivers

The document summarizes information for parents, guardians and caregivers of individuals with autism spectrum disorder regarding:

- Current status of stem cell therapy for ASD
- Established forms of treatment for ASD
- Legal restrictions governing administration of stem cell therapy for ASD
- Caution against misleading claims
- Information regarding participation in clinical trials

1. Current status of stem cell therapy for autism spectrum disorder (ASD)

- Stem cell therapy is an established treatment only for a defined list of conditions approved by the Ministry of Health and Family Welfare. This list is available on the Department of Health Research (DHR) website (https://www.dhr.gov.in). This list may be updated from time to time.
- Stem cell therapy for ASD is not recognized as sound and relevant medical practice and is not an approved treatment. It cannot be offered as a clinical service outside a duly approved and monitored clinical trial setting.

2. Current status of established therapies for ASD:

- ASD is a neurodevelopmental disorder that is characterized by persistent difficulties in social communication and interaction, together with restricted

and repetitive patterns of behaviour, interests or activities. It is multifactorial in origin with no established cure and the spectrum can range from mild to severe. Early identification and early intervention can improve outcomes.

- Existing evidence supports the role of behavioral, developmental, and educational interventions as the primary modalities for management of ASD in children. These include early behavioural and developmental intervention, parent-mediated intervention, speech and language therapy, occupational therapy and special education, planned according to the needs of each child.
- Pharmacotherapy may sometimes be used for associated medical or mental health conditions such as irritability, hyperactivity, sleep problems or epilepsy. No medicine treats the core features of autism.

3. Legal restrictions governing administration of stem cell therapy for ASD

- Stem cell therapy for ASD is permissible only as part of a duly approved and monitored clinical trial. A clinical trial is a type of research conducted on human participants to evaluate the safety and efficacy of an intervention. Permission to conduct or participate in a clinical trial does not mean that the treatment has been proven safe and effective or is approved for routine clinical use. A clinic or hospital offering stem cell therapy as part of a clinical trial does not, by itself, establish that the treatment is approved for ASD. Stem cell therapy is currently not an approved form of treatment for ASD.
- All clinical trials must have the required approvals and oversight. This includes review and approval by a duly registered Ethics Committee and endorsement by the National Stem Cell Research Regulation Committee (NSRC) constituted by DHR, if the stem cells used have undergone minimal or less than minimal manipulation. If the stem cells have undergone more than minimal manipulation, regulatory approval from CDSCO under the New Drugs and Clinical Trials Rules 2019 is required, in addition to approval by an Ethics Committee registered with CDSCO.

- Every clinical trial must also be registered with the Clinical Trials Registry of India (CTRI) before the first participant is enrolled. The registration can be checked at ctri.nic.in.

4. Caution against misleading claims

Be cautious of promises of cure or advertisements claiming that stem cell therapy is proven safe, effective or an approved form of treatment for ASD. Such claims made by clinics, practitioners or commercial organizations are false. Be cautious of advertisements or statements which:

- Claim that stem cell therapy is proven safe or effective for ASD. These are false claims.
- Claim that research or trial approval means the treatment is approved for routine clinical use. Stem cell therapy is currently not an approved treatment for autism.
- Claim that the procedure is safe because it uses the child's own cells. Use of the child's own (autologous) cells does not make an unproven intervention safe or permissible.
- Ask for payment for stem cell therapy, including payment described as a fee for taking part in a study. Participants in an approved trial must not be charged any fee.

5. Information regarding participation in clinical trials

i. What protections apply in research for human participants?

Research involving administration of stem cells must comply with National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, issued by ICMR. These include:

- Written informed consent: Parents or legally authorized representatives must receive appropriate information about the disease and the proposed

intervention and then provide full free and voluntary written consent. Where appropriate, the assent of the child should also be sought. Parents may withdraw their child from the study at any time, without any effect on the usual care of the child.

- No cost to the patient: Anyone taking part in stem cell clinical trial must not be asked to pay for any procedure during the course of the study. This includes the stem cell treatment being studied, tests, procedures, hospital stay or any other research-related costs. This applies to all participants, whether they receive the stem cell intervention, or the comparator treatment.
- Insurance: Before starting any stem cell research in human participants, insurance coverage must be ensured by the host institution/trial site, to provide compensation if a participant suffers an injury, becomes disabled, or dies because of the research.
- Appropriate compensation: Any participant who suffers harm as a result of participation in stem cell clinical trial shall be entitled to appropriate compensation in line with the NDCT Rules, 2019, and the quantum of such compensation shall be adapted from the formulae prescribed in the NDCT Rules, 2019. This applies to all participants, regardless of which group of the study they belong to.
- Before agreeing to participate in a clinical trial, ask about the study design, eligibility criteria, intervention characteristics, possible risks and benefits, available alternatives, and whom to contact with questions or concerns. Make sure you have read and fully understood the consent form before agreeing.

ii. Will everyone in a clinical trial receive stem cell treatment?

Taking part in a stem cell therapy clinical trial does not guarantee that you will receive stem cell treatment or that your child will benefit. In a randomized controlled trial, you may either receive stem cell therapy or the comparator

treatment as per the study design. Before agreeing to participate, make sure you understand the study design and discuss any questions with the research team. The research team should explain how children in every group of the study will be followed up and monitored, and what will happen after the study ends.

iii. Questions to ask before enrolling in a clinical trial:

- Which institutions are conducting the study, and do they have the requisite approvals?
- Is the trial registered with the Clinical Trials Registry of India (CTRI)?
- What are the possible risks, benefits and alternatives?
- Will participation involve any cost to the patient?
- What protections and compensation arrangements apply in case of research-related injury?
- Can I withdraw my child from the study at any time, and will my child's usual care continue?

Make informed decisions regarding treatment for autism:

- Do not stop or delay your child's existing care or developmental support in favor of an unproven intervention. Currently, stem cell therapy for autism can only be given as a part of a duly approved and monitored clinical trial. Discuss treatment decisions and any proposed participation in a clinical trial with a qualified healthcare professional.
- Know the facts. Make informed decisions. Protect your loved ones.
- Your child deserves safe, ethical and evidence-based care. Be informed before making a decision about stem cell intervention.

PARENT & CAREGIVER AWARENESS

STEM CELL THERAPY FOR AUTISM SPECTRUM DISORDER (ASD)

What parents, guardians and caregivers should know

CURRENTLY NOT RECOMMENDED FOR ROUTINE TREATMENT

Stem cell therapy is not an approved treatment for autism. It cannot be offered as a clinical service outside an approved clinical trial.

WHAT SHOULD FAMILIES KNOW ABOUT AUTISM?

There is no established cure for autism. Management mainly involves behavioral, developmental and educational interventions, and early intervention improves outcomes. Medicines may help associated problems but do not treat autism itself.

01 RESEARCH ONLY

Stem cell therapy for ASD is not an approved treatment. It can be given only within a duly approved and monitored clinical trial.

02 KNOW YOUR RIGHTS

Research in human participants must follow ICMR ethical guidelines. There should be written informed consent, cost for any trial-related care must be covered, participants have the freedom to withdraw at any time, and there are provisions for compensation for research-related injury.

03 BEWARE OF MISLEADING CLAIMS

Be cautious of promises of cure or claims that stem cell therapy is proven safe, effective, or approved for treatment of autism. It is experimental and not an approved treatment.

04 CHECK APPROVALS AND OVERSIGHT

A clinical trial must have the required approvals, including review by a duly registered Ethics Committee and approval by the NSRC (minimally manipulated stem cells) or by CDSCO (more than minimally manipulated stem cells), and registration with CTRI.

05 PARTICIPATION DOES NOT GUARANTEE BENEFIT

Depending on the study design, participants may receive either stem cells or a comparator such as usual standard of care. Taking part does not guarantee benefit, even for those who receive stem cells.

06 CHECK BEFORE YOU DECIDE

Discuss the pros and cons of participation with the clinical trial team. Ask about the potential risks, benefits and alternative treatment options. Make sure you fully understand the consent form before agreeing.

ASK QUESTIONS. TAKE YOUR TIME.

What are the eligibility criteria, and is the trial registered with CTRI?
What are the risks and alternatives, and are there any costs involved?
Who can I contact if I have concerns?

MAKE INFORMED DECISIONS.

Protect your loved ones from misleading claims about stem cell therapy for autism.
When in doubt, seek advice from a qualified healthcare professional.

Issued in public interest by the Ministry of Health & Family Welfare. For views regarding participation in the RCT on stem cell therapy for autism, email your views to: suggestions.asd.rct.nsrc@gov.in