



Stem cell

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Recently, Doctors in Mumbai used stem cell therapy to **save life of a premature baby boy**, who was suffering from a chronic lung disease.

Stem Cell

- Stem cells are the **body's raw materials — cells from which all other cells with specialized functions are generated.**
- Under certain conditions in the body or a laboratory, stem cells divide to form more cells **called daughter cells.**
 - These daughter cells either become **new stem cells (self-renewal)** or become **specialized cells (differentiation)** with a more specific function, such as blood cells, brain cells, heart muscle cells or bone cells.
 - No other cell in the body has the natural ability to generate new cell types.
- What is stem cell therapy?
 - Stem cell therapy, also known as **regenerative medicine**, promotes the repair response of diseased, dysfunctional or injured tissue using stem cells or their derivatives.
 - Stem cells can then be **implanted into a person.** For example Mumbai baby boy was injected with 40 million stem cells and gradually the lungs began to repair. In this case, doctors used mesenchymal stem-cell therapy (these are adult stem cells and are different from Embryonic stem cells) on an experimental basis
- Why it is an issue?

In March 2019, the Union Health Ministry had notified the **'New Drugs and Clinical Trial Rules, 2019'** which state that stem-cell **derived products are to be used as "new drugs"**. "This means that any doctor who uses stem-cell therapy needs to take permission from the government.

Clinical Trial Regulations In India

- **Central Drugs Standard Control Organization (CDSCO)** which comes under the

Ministry of Health and Family Welfare is the main body which works on development of regulatory procedures and standards for drugs, cosmetics, diagnostics and devices.

- It lays down regulatory **guidance by amending acts and rules**; and regulates new drug approval process.
- Its main objective is to standardize clinical research and bring safer drugs to the Indian market.
- The **Drug Controller General of India (DCGI)** is responsible for giving regulatory permissions for the conduct of clinical trials and is responsible for approval of marketing licenses for drugs in India.