Stem Cell Therapies for Neurodevelopmental Disorders

A. BOROUMAND

NEUROLOGIST,

FELLOWSHIP IN PSYCHOSOMATIC MEDICINE – FREIBURG – GERMANY

FELLOWSHIP IN REGENERATIVE MEDICINE – MÜNSTER - GERMANY

Stem cell therapy on the way

- Stem Cell therapy for ALS patients also have FDA-approval in South Chorea.

profile biopharmadealmakers

CORESTEM

www.corestem.com

CORESTEM

First licensed stem cell therapy for ALS

CORESTEM launched the world's first stem cell therapy for amyotrophic lateral sclerosis in South Korea in 2015. The company is now seeking out-licensing partners as it works toward product approvals in the US and Europe.

CORESTEM is a biotechnology company specializing in the research and development of personalized stem cell therapies for neurological and autoimmune diseases. Its lead product is NeuroNata-R (lenzumestrocel), the world's first stem cell-based therapy for amyotrophic lateral sclerosis (ALS).

NeuroNata-R was approved as an orphan drug for the treatment of ALS by the Ministry of Food and Drug Safety (MFDS) in South Korea in 2014. "Back then there were no ground rules laid out by the MFDS for stem cell therapy, so CORESTEM has been paving the way in this regard, and the path we took was adopted by the MFDS as regulatory guidelines," said KyungSuk Kim, CEO of CORESTEM.

ALS, also known as Lou Gehrig's disease or motor neuron disease, is a progressive neurodegenerative disease that leads to muscle atrophy due to the death of motor neurons. The average life expectancy is three to five years after the onset of disease. The only approved treatments for ALS outside South Korea are the small-molecule drugs riluzole and edaravone.

NeuroNata-R is based on autologous bone marrow-derived mesenchymal stem cells (MSCs). Treatment

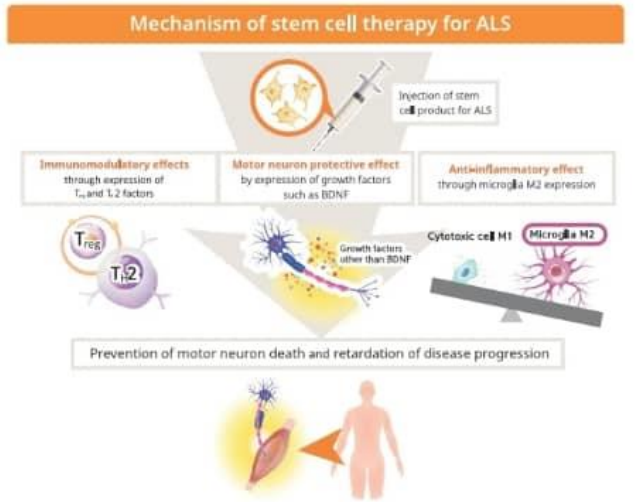


Fig. 1 | NeuroNata-R is a stem cell therapy approved in South Korea for ALS. NeuroNata-R has various effects that prevent motor neuron death and slow disease progression in patients with amyotrophic lateral sclerosis (ALS)[1–3]. BDNF, brain-derived neurotrophic factor; T_H2, T helper 2; T_{reg}, regulatory T.

Stem cell therapy on the way

- Recently, Japanese authorities cleared a mesenchymal stem cell (MSC) product for treating spinal cord injuries.

this is the ***second*** approved for treating a neurological condition.

- Ref: Cyranoski D. Japan's approval of stem-cell treatment for spinal-cord injury concerns scientists. Nature 2019;565(7741):544-545. https://doi.org/10.1038/d41586-019-00178-x

What is stem cell

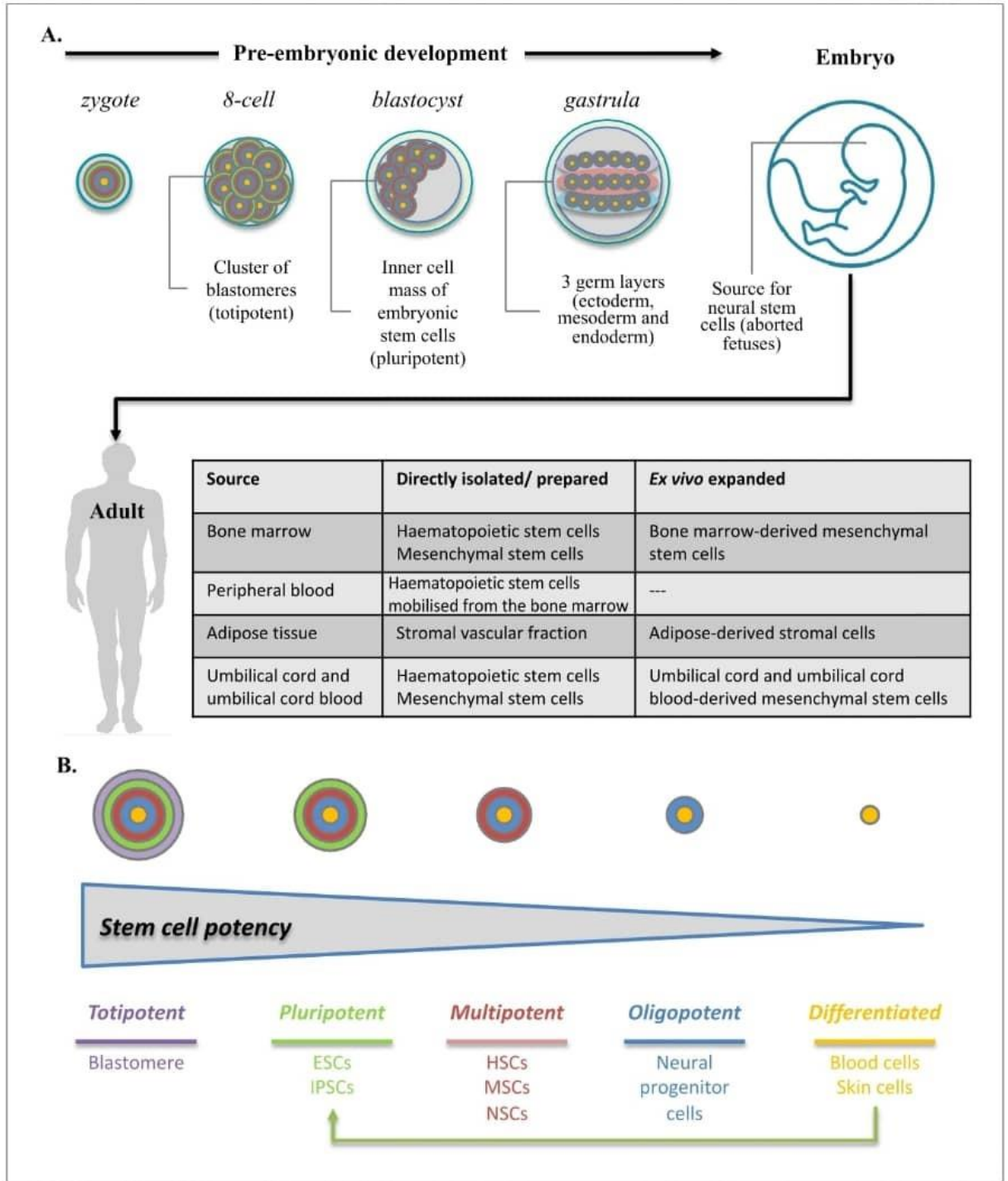
- ***Stem cells provide the building blocks for every organ in the body***.
- ***Property of stem cells***:
  1. divide asymmetrically
  2. differentiate into the various cell types of the body
  3. simultaneously replicating to maintain a stem cell lineage.

- ***Stem cells are present in almost every human tissue:***
  1. in embryos, they differentiate into all the tissues and organs of the body.
  2. in fully developed humans they provide a renewal capacity in most organs.

- Different forms of stem cells exist, each with a varying 'potency' (Fig. 1).

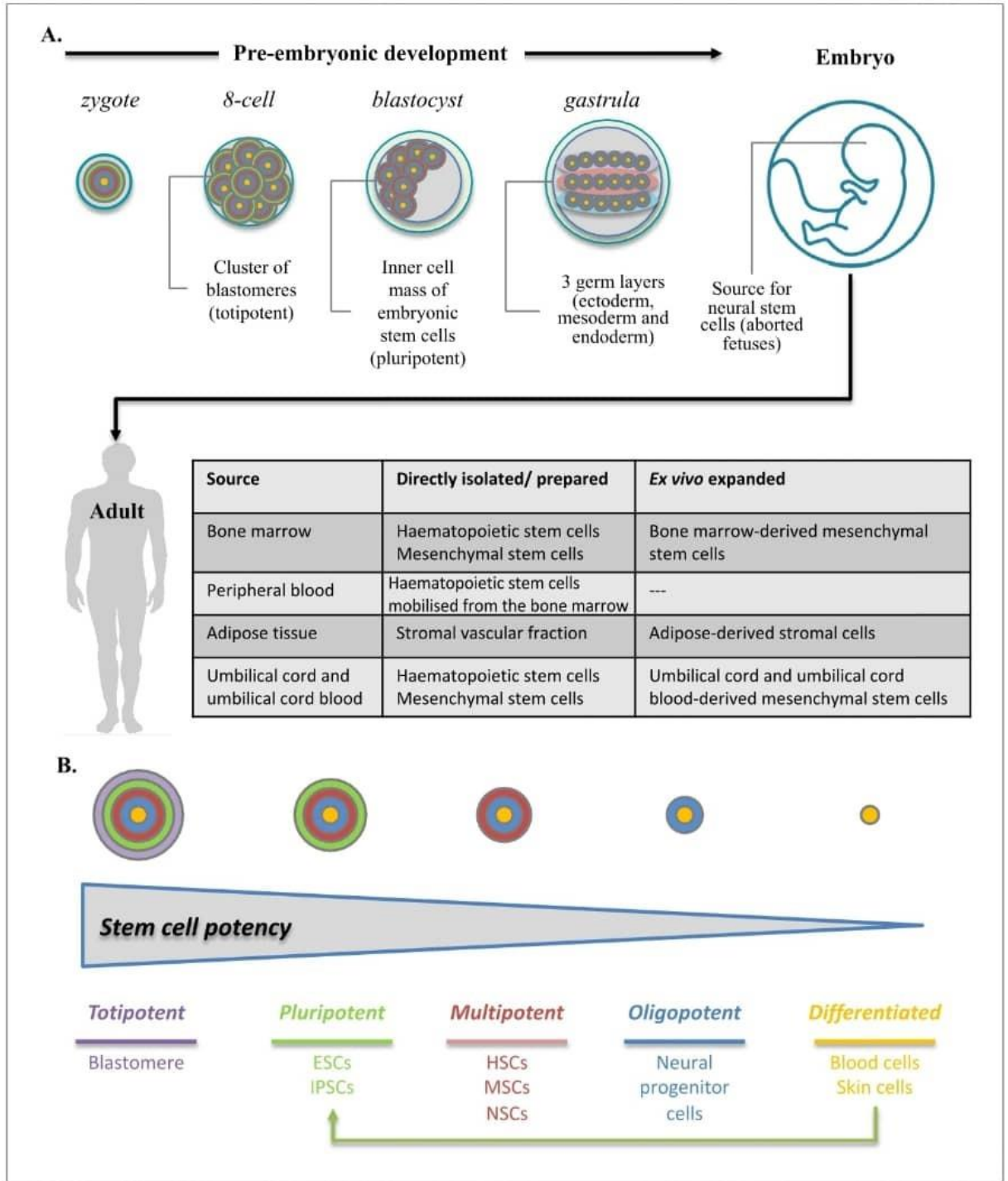
Stem Cell Types:

- There are different types of stem cells which classified based on their potency to replicate and differentiate to different types of cell….



Stem Cell Types:

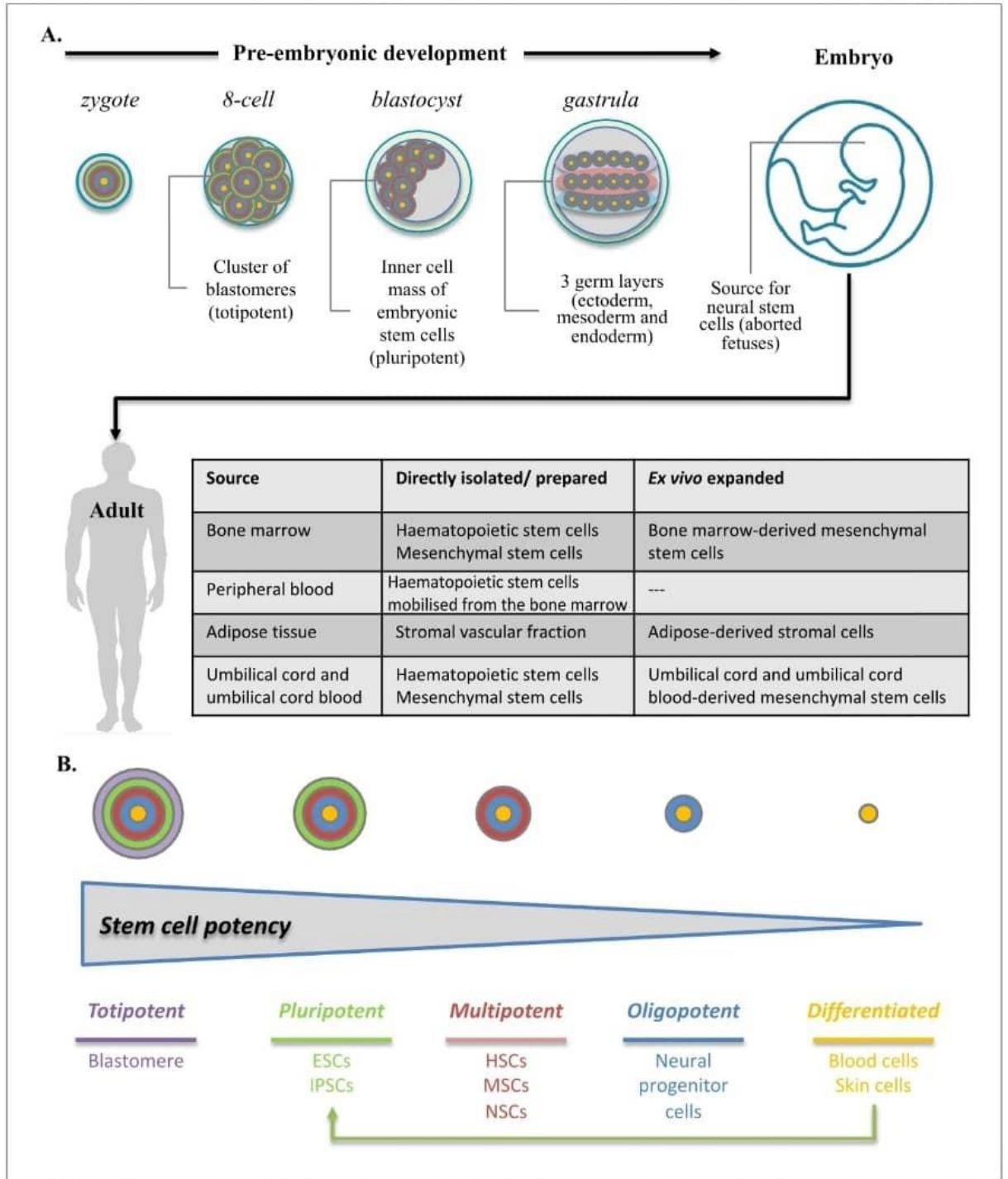
- Totipotent and pluripotent stem cells
- have the highest potency, and are obtained from the pre-embryonic stages of development.
- Blastomeres that arise from a fertilised ovum (zygote) are totipotent stem cells and have the potential to differentiate into all organs of the body, including the placenta.



Source	Directly isolated/ prepared	*Ex vivo* expanded
Bone marrow	Haematopoietic stem cells Mesenchymal stem cells	Bone marrow-derived mesenchymal stem cells
Peripheral blood	Haematopoietic stem cells mobilised from the bone marrow	---
Adipose tissue	Stromal vascular fraction	Adipose-derived stromal cells
Umbilical cord and umbilical cord blood	Haematopoietic stem cells Mesenchymal stem cells	Umbilical cord and umbilical cord blood-derived mesenchymal stem cells

Stem Cell Types:

- A cluster of blastomeres goes on to form a blastocyst, which has a hollow cavity and an inner cell mass of embryonic stem cells (ESCs).
- These stem cells are ***pluripotent*** in nature and, relative to totipotent stem cells→ have lost the ability to differentiate into the placenta while maintaining their ability to form all organs and tissues of the body.
- A blastocyst develops into a gastrula wherein the three germ layers have started to form, followed by the development of an embryo.



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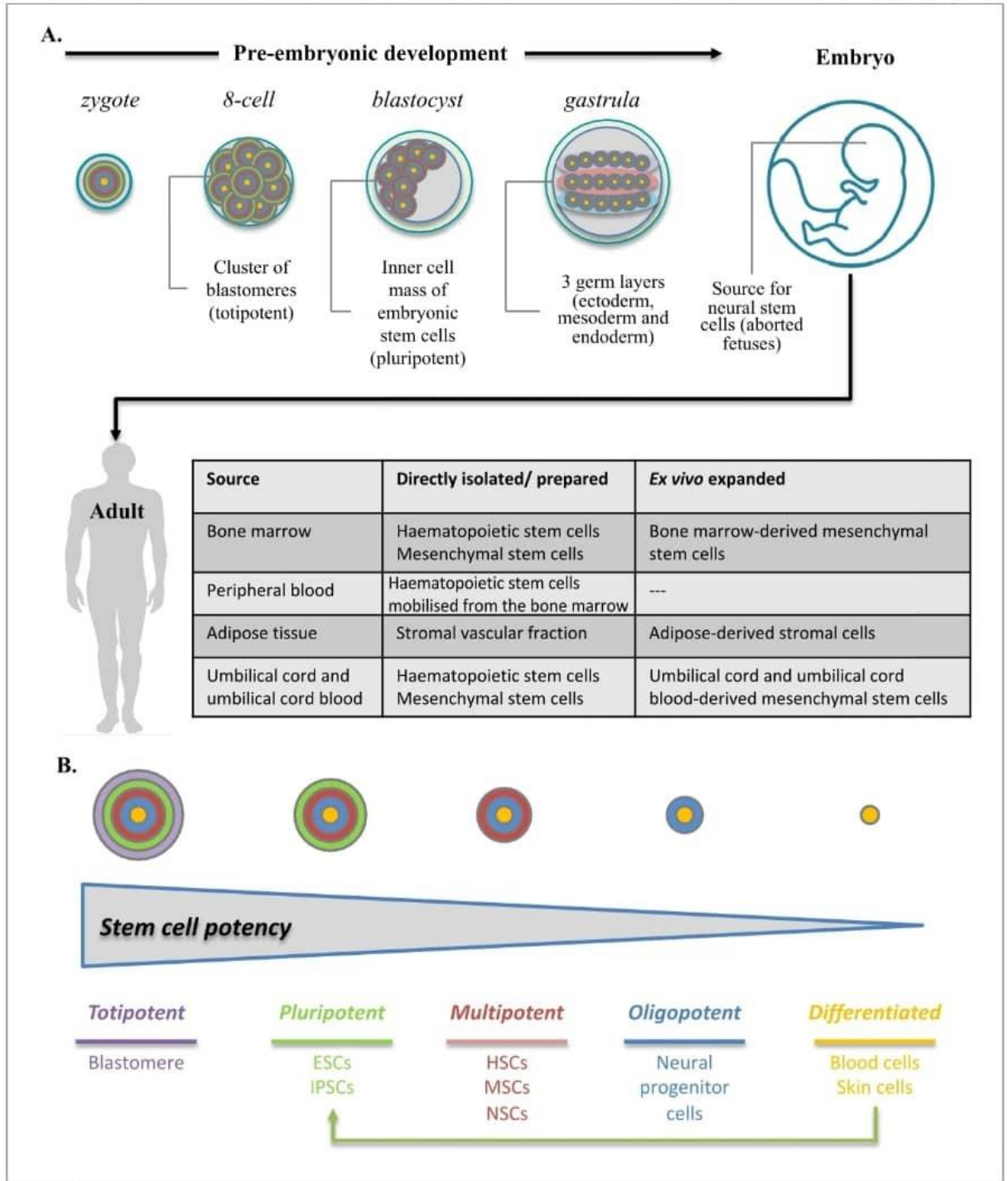
Stem Cell Types:

- Pluripotent stem cells differentiate into ***multipotent stem cells***, including
  1. HSCs,
  2. MSCs
  3. Neural stem cells (NSCs).

- These cells are committed to further differentiate into cells of a given organ or system
  - HSCs differentiate into cells of the blood and immune systems
  - NSCs into cells of the brain and nervous

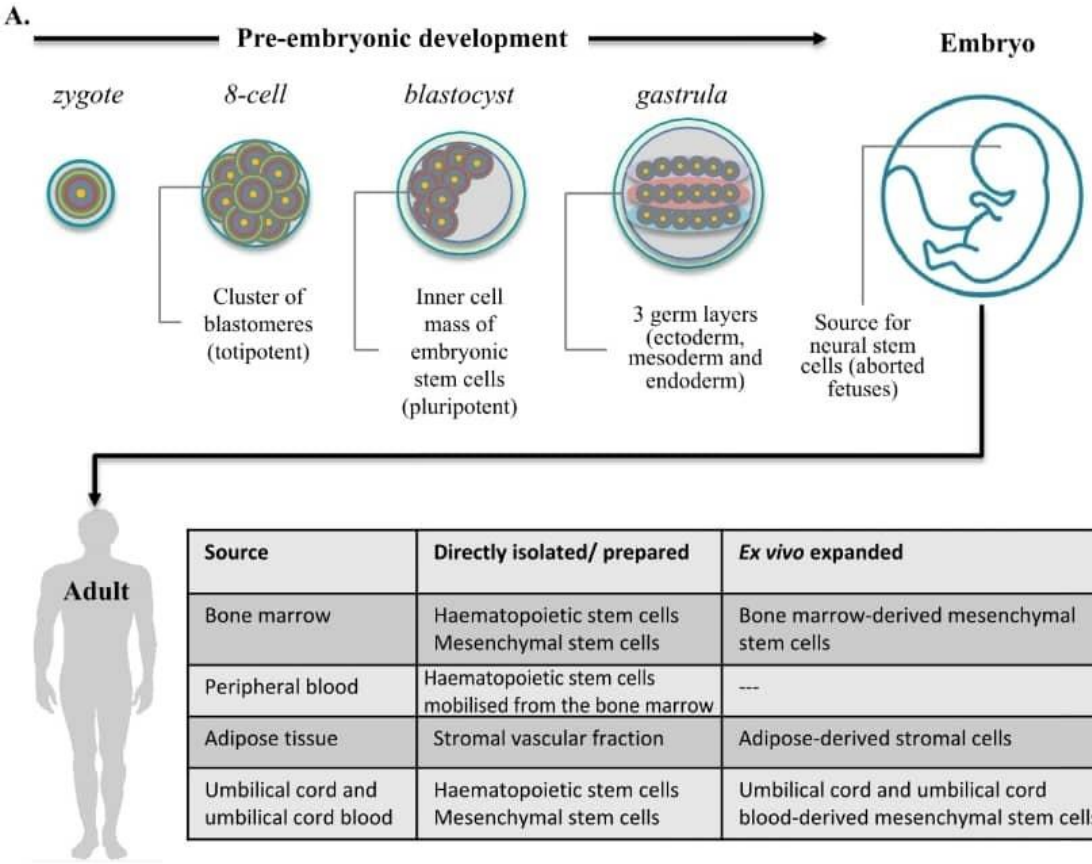


Stem Cell Types:

- Until recently, stem cell differentiation was considered unidirectional

by introducing a defined number of factors into fully differentiated cells (e.g. skin or blood cells) in a laboratory setting, one is able to derive a cell type which once again has pluripotent capacity

induced pluripotent stem cells (iPSCs).



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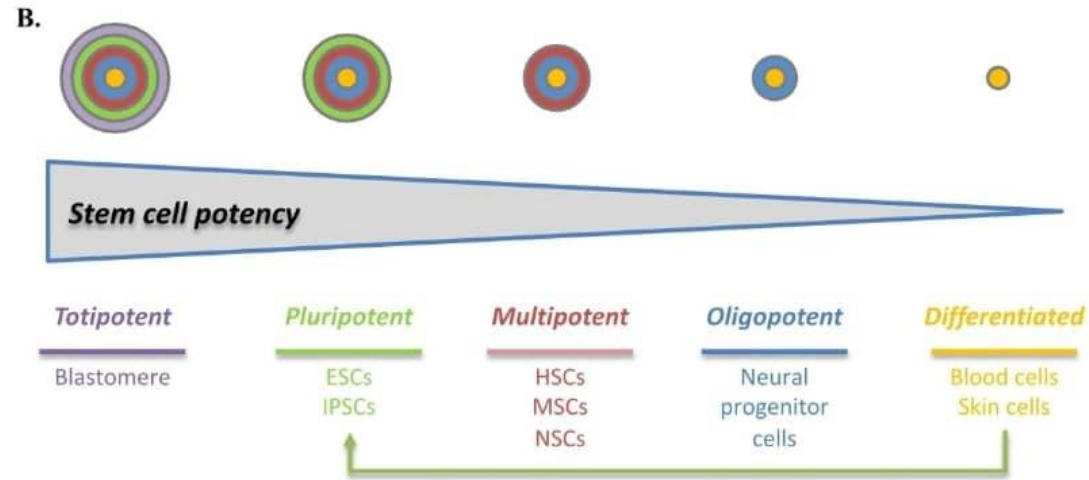

Stem Cell source in adults

Source	Directly isolated/ prepared	*Ex vivo* expanded
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Peripheral blood	Haematopoietic stem cells mobilised from the bone marrow	---
Adipose tissue	Stromal vascular fraction	Adipose-derived stromal cells
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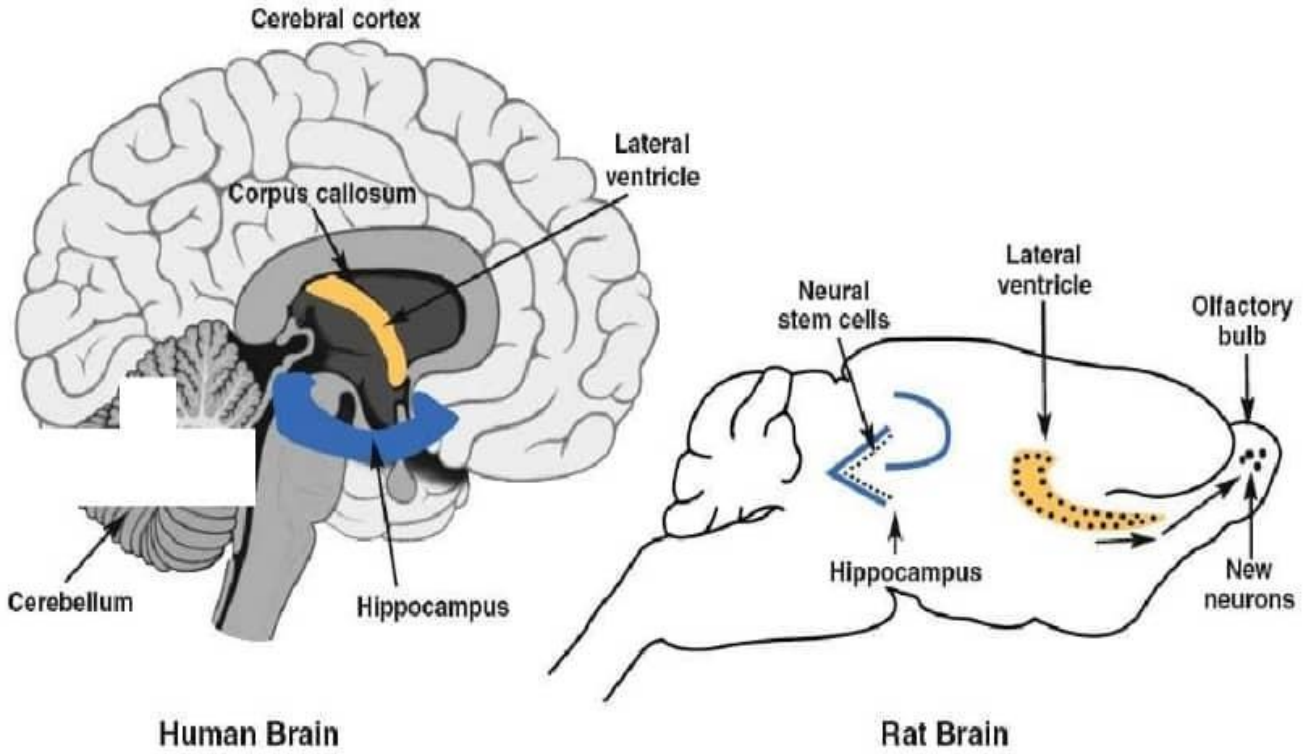
BMMSCs Vs. UCMSCs

- Another rich source of stem cells is bone marrow, but cells harvested from bone marrow have characteristics that distinguish them from those from cord blood.
  1. bone-marrow-derived cells from adults are more immunogenic
  2. are more likely to carry latent viruses that are difficult to detect in assays.
  3. They are characterized by shorter telomeres and lower proliferative potential.
  4. Bone marrow cells are harvested during a surgical procedure under general anesthesia that takes about an hour.

Neural Stem Cell source in adults

SITES OF ADULT NEURONAL STEM CELLS

Subventricular zone(SVZ) of lateral ventricles and the Subgranular zone of dentate gyrus in hippocampus.



Kornblurm HI. Introduction to neural stem cells. Stroke,2007,38: 810.

Mechanisms of action of different Stem cells for Neurological disorders :

Table 1. Different stem cells, related sources, and their mechanisms of action [60–70,72–78,81,83,90].

Type of Stem Cells	Source	Mechanism of Action
Fetal stem cells	Fetus, fetal blood, placenta, amniotic membrane, amniotic fluid, umbilical cord	Secretion of neurotrophic factors, immunomodulatory capacities, suppression of proinflammatory processes
Mesenchymal stem cells	Bone marrow, umbilical cord	Paracrine secretion of several anti-inflammatory and survival-promoting molecules (i.e., VEGF, HGF, BDNF, NGF), neuroprotective effects, hypoimmunogenic and immunosuppressive properties
Neural stem cells	Brain (subventricular zone of lateral ventricles and subgranular zone of hippocampus)	Secretion of neurotrophic factors, maintenance of homeostasis, neuroprotective effects, differentiation into neural-type cells
Adipo-derived stem cells	Adipose tissue	Secretion of trophic factors Immunosuppressive and hypoimmunogenic effects
Umbilical cord- and amniotic fluid-derived stem cells	Umbilical cord, placenta, amniotic fluid	In vitro growth capacity, low immunogenicity and immunomodulation properties
Hematopoietic stem cells	Blood, bone marrow, umbilical cord	Paracrine activity
Induced pluripotent stem cells	Any cell type	Differentiation capacity

Abbreviations: VEGF = vascular endothelial growth factor; HGF = hepatocyte growth factor; BDNF = brain-derived neurotrophic factor; NGF = nerve growth factor.

Advantages and disadvantages of any type

Table 1. Advantages and disadvantages of the different stem cell types

Stem cells	Advantages	Disadvantages
NSCs	Prototype stem cells for treating neurological disease	Limited resource with ethical implications around procurement (if from aborted fetal tissue)
	NSC-like cells can be derived from other stem cell types (pluripotent and multipotent)	Poorly understood stem cell biology and least explored in clinical studies
		Tumorigenic risks if derived from pluripotent stem cells
HSCs	Globally accepted form of treatment for haematological conditions	Limited experience for use in neurological disease
	Well-established industry for harvesting and preparation of clinical grade treatments	Generally limited for use as an autologous therapy (requires genetic matching of the donor and recipient if used as an allogeneic treatment)
		Poorly understood mechanism of action for treating certain neurological conditions
MSCs	Readily accessible resource and easily procured	Exploited by unregulated clinics globally
	No need for genetic matching	Poorly understood mechanism of action for treating certain neurological conditions
	Most likely stem cell therapy to evolve into an off-the-shelf allogenic product	

NSCs = neural stem cells; HSCs = haematopoietic stem cells; MSCs = mesenchymal stem cells.

Stem cell therapy for Neurological and neurodevelopmental disorders

- What is the goal of treatment in neurological disorders:

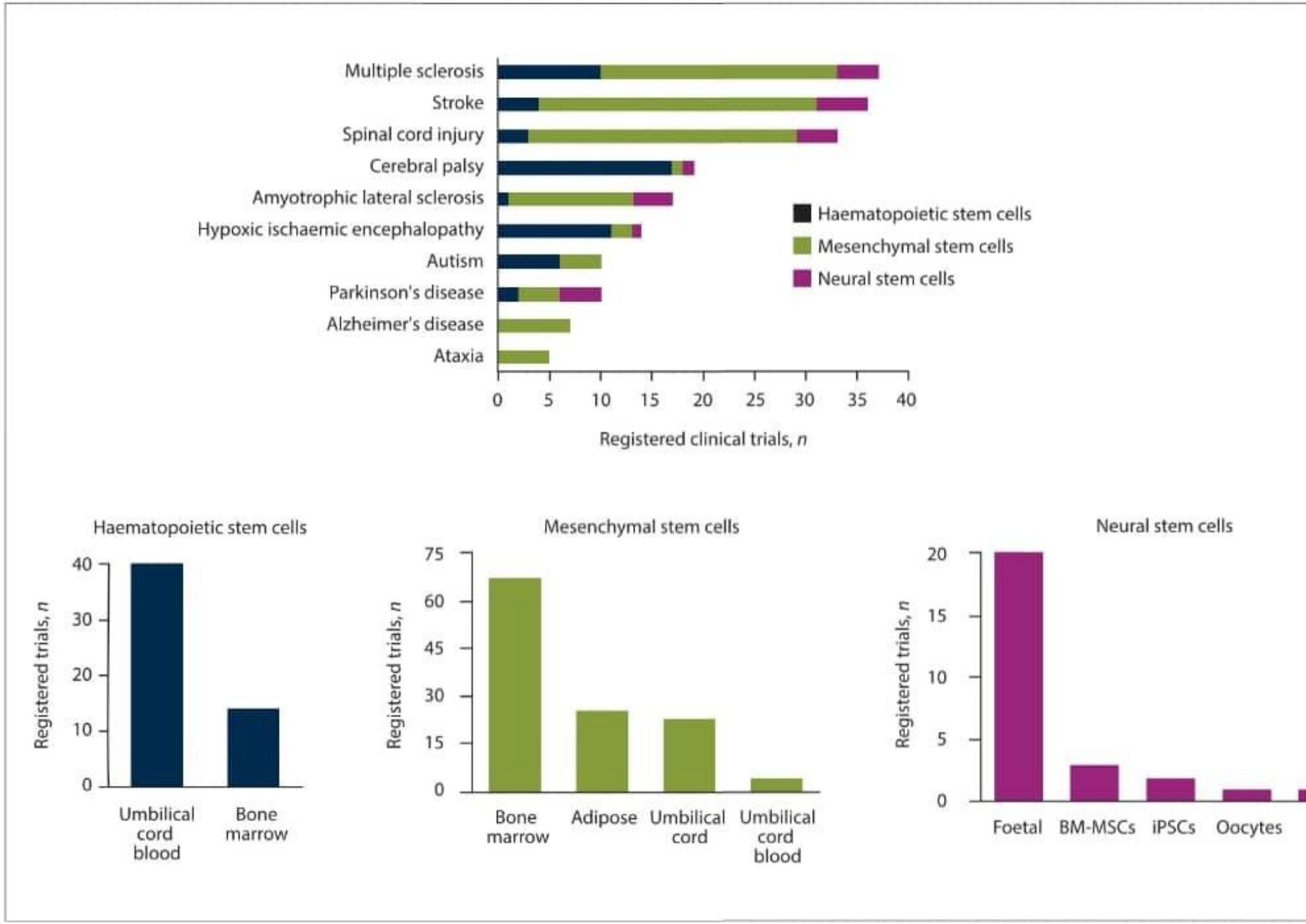
1. preventing more damage to nerve cells (Stroke)
2. Improving tissue score in central nervous system - (ALS, CP,)
3. preventing scar tissue formation in CNS/PNS (SCI)
4. modulating immune system against CNS/PNS (MS+ALS, ASD)
5. replacing new neuronal cells to repair CNS/PNS (AD, PD, SCI, ALS, CP, …..)
6. activating other neural stem cells to improved damaged CNS (SCI, CP, ASD) – bio bridging
7. Poorfeeding in CNS (AD, PD,ASD, CP….) → Pingponging
8. Improving Oligodendrocyte Activity (Dysmyelination) → HIE, CP
9. Angigenesis
10. Neurogenesis – Prolifration, Migration, Integration, Differentiation, Survival

Neurogenesis by Stem cells

- Neurogenesis has 5 steps:
  1. Prolifration
  2. Migration
  3. Integration
  4. Differentiation
  5. Survival

- Clinical trials – 2023
- Source : Clinicaltrials.gov

Clinical Trials registered in clinicaltrials.gov



Clinical trials in 2021 in China

16 is in progress

Clinical trial in china

ClinicalTrials.gov Search Results 02/17/2021

	Title	Status	Study Results	Conditions	Interventions	Locations
1	Safety and Efficacy of Umbilical Cord Mesenchymal Stem Cell Therapy for Patients With Progressive Multiple Sclerosis and Neuromyelitis Optica	Unknown status	No Results Available	•Progressive Multiple Sclerosis •Neuromyelitis Optica	•Biological: human umbilical cord mesenchymal stem cells	•Nanjing University Medical College Affiliated Drum Tower Hospital, Nanjing, Jiangsu, China
2	Human Umbilical Cord Mesenchymal Stem Cell Therapy for Cerebral Infarction Patients in Convalescent Period	Suspended	No Results Available	•Cerebral Infarction	•Biological: Allogeneic umbilical cord mesenchymal stem cell •Drug: Aspirin Enteric-coated Tablets & Atorvastatin Calcium	•Inner Mongolia International Mongolian Hospital, Hohhot, Inner Mongolia, China
3	Safety and Efficacy of Umbilical Cord Mesenchymal Stem Cell Therapy for Patients With Hereditary Ataxia	Unknown status	No Results Available	•Hereditary Ataxia	•Biological: human umbilical cord mesenchymal stem cells	•Nanjing University Medical College Affiliated Drum Tower Hospital, Nanjing, Jiangsu, China
4	Safety and Efficacy of Umbilical Cord Mesenchymal Stem Cell Therapy for Patients With Duchenne Muscular Dystrophy	Unknown status	No Results Available	•Duchenne Muscular Dystrophy	•Biological: human umbilical cord mesenchymal stem cells	•The Second Affiliated Hospital of Kunming Medical College, Kunming, Yunnan, China
5	Umbilical Cord Derived Mesenchymal Stem Cells Therapy in Hypoxic Ischemic Encephalopathy	Unknown status	No Results Available	•Hypoxic Ischemic Encephalopathy	•Biological: mesenchymal stem cells	•the First Hospital of Hebei Medical University, Shijiazhuang, Hebei, China
6	Umbilical Cord Derived Mesenchymal Stem Cells Therapy in Parkinson's Disease	Enrolling by invitation	No Results Available	•Parkinson's Disease	•Biological: mesenchymal stem cells	•Hebei Newtherapy Bio-Pharma Technology Co., Ltd, Shijiazhuang, Hebei, China
7	Human Umbilical Cord Mesenchymal Stem Cell in Cerebral Hemorrhage Sequela	Unknown status	No Results Available	•Cerebral Hemorrhage	•Biological: Human umbilical cord mesenchymal stem cells	•The Fifth Affiliated Hospital immunotherapy center, Guangzhou, Guangdong, China
8	Umbilical Cord Derived Mesenchymal Stem Cells Treatment in Ischemic Stroke	Unknown status	No Results Available	•Stroke	•Biological: Human umbilical cord mesenchymal stem cells	•Department of Neurosurgery,Affiliated Hospital of Academy of Military Medical Sciences(307 Hospital), Beijing, Beijing, China
9	Difference Between Rehabilitation Therapy and Stem Cells Transplantation in Patients With Spinal Cord Injury in China	Unknown status	No Results Available	•Spinal Cord Injuries	•Procedure: rehabilitation of limb function •Procedure: Stem Cells Transplantation	•Yihua An, Beijing, China
10	Different Efficacy Between Rehabilitation Therapy and Stem Cells Transplantation in Patients With SCI in China	Completed	No Results Available	•Spinal Cord Injury	•Biological: cell therapy •Other: rehabilitation	•General Hospital of Chinese People's Armed Police Forces, Beijing, Beijing, China
11	Autologous Mesenchymal Stem Cells for the Treatment of Neuromyelitis Optica Spectrum Disorders	Completed	No Results Available	•Devic's Syndrome •Devic's Neuromyelitis Optica •Devic Syndrome •Devic's Disease •Devic Disease	•Biological: Autologous mesenchymal stem cells	•Tianjin Medical University General Hospital, Tianjin, Tianjin, China
12	Efficacy of Stem Cell Transplantation Compared to Rehabilitation Treatment of Patients With Cerebral Paralysis	Completed	No Results Available	•Cerebral Palsy	•Other: rehabilitation •Biological: stem cell injection	•General Hospital of Chinese People's Armed Police Forces, Beijing, Beijing, China
13	Autologous Hematopoietic Stem Cell Gene Therapy for Metachromatic Leukodystrophy and Adrenoleukodystrophy	Recruiting	No Results Available	•Metachromatic Leukodystrophy •Adrenoleukodystrophy	•Genetic: transduced CD34+ hematopoietic stem cell	•Shenzhen Second People's Hospital, The First Affiliated Hospital of Shenzhen University, Shenzhen, Guangdong, China
14	The Safety and Efficacy of Human Umbilical Cord Mesenchymal Stem Cells in the Treatment of Acute Cerebral Infarction	Suspended	No Results Available	•Cerebral Infarction	•Biological: Allogeneic umbilical cord mesenchymal stem cells (SCLnow 194) •Drug: Aspirin Tablet	•Inner Mongolia International Mongolian Hospital, Hohhot, Inner Mongolia, China
15	Intracerebral Transplantation of Neural Stem Cells for the Treatment of Ischemic Stroke	Unknown status	No Results Available	•Ischemic Motor Stroke, Chronic	•Drug: NSI-566	•Ba Yi Brain Hospital, Beijing, China
16	Autologous Bone Marrow Mesenchymal Stem Cell Transplantation for Chronic Stroke	Unknown status	No Results Available	•Stroke	•Genetic: intracerebral stem cell transplantation	•The First Affiliated Hospital of Wenzhou Medical College, Wenzhou, Zhejiang, China

Clinical trials in 2022 in USA

58 is in progress

Types of stem cell in neurological diseases

1. Neural Stem Cells
2. Mesenchymal stem cells
3. HSCs

Tumerogenicity of MSCs:

- Treatment with MSCs is characterized by high safety as clearly shown in a meta-analysis and systematic review published in 2018, based on 36 studies conducted in 14 countries around the world, involving more than 1000 recipients with various diseases.

- Effects of stem cells on other Tumors…

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Neurodevelopmental Disorders

- Autism
- Cerebral palsy

Autism Spectrum Disorders

Autism Spectrum Disorders

- Autism spectrum disorder (ASD) is a heterogeneous neurodevelopmental condition with aspecific combination of impairments in :

  - social communication and interaction,
  - sensory anomalies,
  - repetitive behaviours
  - varying levels of intellectual disability beginning early in life(Lordet al.,2018,2020).

15 Dec. 2023-WHO Key facts for ASD

- Autism – also referred to as autism spectrum disorder–constitutes a diverse group of conditions related to development of the brain.
- About 1 in 100 children has autism.
- Characteristics may be detected in early childhood, but autism is often not diagnosed until much later.
- The abilities and needs of autistic people vary and can evolve over time. While some people with autism can live independently, others have severe disabilities and require life-long care and support.
- Evidence-based psychosocial interventions can improve communication and social skills, with a positive impact on the well-being and quality of life of both autistic people and their caregivers.

Huge amount of financial burden in ASD:

- **Unfortunately**, the impairments of ASD usually continue into adulthood in most cases,which may lead to
  - limited social integration of patients,
  - poor employment prospects,
  - a high incidence of mental health problems
  - a low workforce participation rate of parents or caregivers (Doranet al.,2012; Howlin and Magiati,2017).

The estimated financial burdenof supporting an individual with ASD and intellectual disability across his or her lifespan amounts to ***2.4 million dollars in the USA*** (Buescheret al.,2014).

Autism Spectrum Dosorders

- ICD-10 / DSM-5 autism spectrum disorder (ASD) is defined as:

  a communication/social interaction disorder with associated repetitive behaviors .

- ASD includes various neurodevelopmental disorders with diverse etiologies such as
  1. Autistic Disorder,
  2. Pervasive Developmental Disorder not Otherwise Specified (PDD-NOS),
  3. Asperger's Disorder.

- Overall prevalence of ASD → 1.5% to 1.8% and an increase has been reported around the world over the past decade .
- Males show a prevalence of 2.8% and females a prevalence of 0.65%, making the male-to-female ratio of 4.3:1

Pathomechanisms of ASD:

- A combination of genetic, environmental and immunological factors underlie ASD.
- It is estimated that up to 1000 potential genes are involved in the genetic determinants of ASD, which are linked by multiple (familial) patterns of inheritance.
- Most of them are responsible for the most essential processes in brain organization and function, such as:
  - **synaptogenesis**,
  - **neurotransmitter metabolism (Neurometabolism)**
  - **alterations in GABAergic circuits** in ASD; this evidence comes from postmortem studies showing: (More association with seizures)→ High Co-morbidity of ASD and Epilepsy
    a) significantly reduced GAD65/GAD67 levels → synthesizes the inhibitory, GABA in the parietal cortex and cerebellum
    b) alterations in $GABA_A$ and $GABA_B$ receptors
  - **changes in the glutamatergic circuit**,→An increase in excitatory synapse number and spine density.

In ASD Brain:

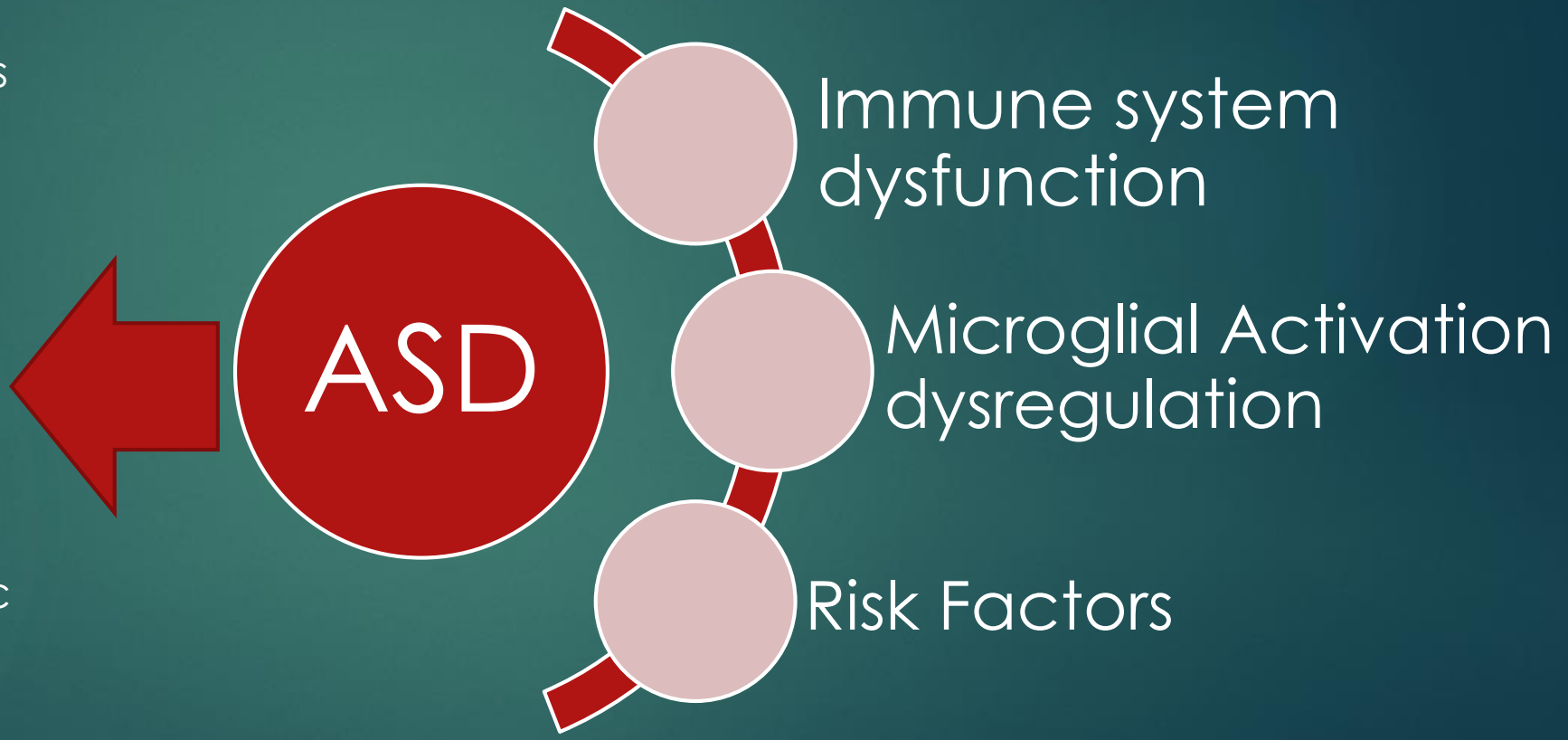
1. • heterogeneous alterations in glutamatergic and GABAergic systems
2. • an overall increased arousal/inhibition ratio,
3. • may manifest as epileptic symptoms,
   • macroscopic brain volume changes
   • behavioral changes

Risk Factors for ASD:

- Many risk factors for autism spectrum disorders are known, mainly related to maternal exposure before and during pregnancy.
  1. exposure to chemicals (e.g., toluene, pesticides),
  2. exposure to heavy metals (arsenate, mercury, lead),
  3. perinatal trauma,
  4. Perinatal infections,
  5. Hypoxia
  6. preterm delivery

Early Brain-immune system dysrgulation

- restrict range of activities
- impairments in social communication,
- concentration disorders,
- sleep disorders,
- hyperactivity,
- motor disorders (e.g., clumsiness or hypotonia)
- disorders of normal functioning of the digestive system (chronic constipation and/or diarrhea)



ASD Treatment

- psychological interventions,
- occupational therapy,
- speech therapy,
- behavioral therapy
- pharmacotherapy (e.g., SSRIs, antipsychotics)

side effects such as extrapyramidal symptoms, sedation, and weight gain

significantly reduce the patients' quality of life

Through functional impairment

dependence on caregivers and facilities

Effects of MSCs on ASD brain:

- ability to produce and release
- the chemokines CXCl4,
- cytokines (e.g., anti-inflammatory IL-10 and IL-1Ra),
- growth factors (e.g., transforming growth factorβ1, TGF-β1 or granulocyte-macrophage colony-stimulating factor, GM-CSF), which decreases or stops the proinflammation

Mechanisms of action of different Stem cells for ASD:

Table 2. Stem cell mechanisms of action in ASD [102–106].

Process	Mechanism of Action
Reduction of inflammation	• Immune modulation and neuroprotective effects • Inhibition of microglial activation and reduction of proinflammatory cytokinesproduction [102,103,106,107]
Restoration of neural connectivity	• Modulation of the excitation and inhibition of neurons by controlling the secretion of neurotransmitters [107] • Re-establishment of neural connectivity by new synapse formation [10]
Angiogenesis	• Reversion hypoxia caused by hypoperfusion in autism • Paracrine activity stimulation endogenous cells, promotion of angiogenesis and differentiation of endothelial cells • Formation of new blood vessels reverse hypoxia [105]
Antioxidant activity	• Reduction of the superoxide production [105]

Cerebral Palsy

A very similar condition with ASD

Cerebral Palsy

- A group of permanent movement and posture disorders caused by anomalies in the developing brain.

- These disorders are most often accompanied by
  - Sensory Problems
  - Perceptual Problems
  - cognitive Problems
  - Visual Problems
  - hearing problems,
  - epilepsy
  - musculoskeletal problems

- The overall prevalence of CP is about 2–3 cases per 1000 births (higher in children born prematurely.

- The prevalence rate reaches higher values in developing countries.

Cerebral Palsy

- The etiology is still unknown, but a complex contribution of
  1. genetic,
  2. prenatal factors (such as hypoxia, intrauterine growth restriction, or infection)
  3. prematurity is suspected
  4. However, in about 80% of cases are considered idiopathic

It is suspected that CP patients develop persistent inflammation of the nervous system and subsequent apoptosis, which usually occurs as a result of *hypoxia-induced trauma*

Cerebral Palsy Treatment

- Treatment includes the use of
- neurotrophic drugs,
- physiotherapy,
- rehabilitation,
- surgical procedures (such as neurectomy and rhizotomy)
- intramuscular injections of botulinum toxin,
- Caregivers' Support

Effectiveness of therapies is limited because none of the treatments target brain damage

Therefore, new therapeutic options are needed that could repair damaged neural tissues, which would improve patients' quality of life by improving motor function

How SCT can help cerebral plasy:

- Improving local stem cells activity → Bio-bridge
- Improvement of oligodendrocyte activity (Dysmyelination)
- Regenerative abilities. Once engrafted, the transplanted cells can proliferate.
- Anti-inflammatory qualities as they cause a reduction in the number of excitotoxins, cytotoxins, and oxygen free radicals.
- Their trophic abilities can reestablish balance between neurotrophic factors.