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Human Albumin Solution Infusion (HAS) - Guideline for practice

SharePoint Location	Clinical Policies and Guidelines
SharePoint Index Directory	General Policies and Guidelines
Sub Area	Haematology and Blood Transfusion
Key words *(for search purposes)*	Human Albumin Solution, HAS
Central Index No	0659 V1
Endorsing Body	Hospital Transfusion Committee
Endorsement Date	September 2010
Review Date	September 2013
Lead author and designation	Dr N Kumar, Consultant Gastroenterologist
(if under review) Review led by	

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KEY POINTS: - This document

- Provides guidance for clinicians on when to request human albumin
- Provides guidance on the indications and contraindications for use
- Provides guidance on monitoring the patient and complications which may occur.

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Index

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Background
In 1998 the Cochrane Injuries Group published a meta-analysis of clinical trials in critically ill patients treated with albumin which showed a 6% increase in mortality compared to patients who had received crystalloids or no treatment.
There are no formal guidelines for use of crystalloids, albumin or other colloid solutions in the United Kingdom

Purpose and scope of policy
1) To provide guidance to clinicians when making the decision to prescribe Human Albumin Solution.
2) To ensure that Human Albumin Solution is prescribed only when clinically indicated and alternatives have been explored and rejected as inappropriate / ineffective.
3) To provide a benchmark for clinical audit.

This guideline is to be used by all staff involved in the prescription and administration of human albumin solution (HAS)

1 Definition of Terms
HAS- Human Albumin Solution

2.1 Process
The issue and use of HAS in those patients which require it.

2.2 Content

2.2.1 Consent
Appropriate consent from the patient must be obtained before administration of HAS as it is a blood product. Patients with certain beliefs, therefore, may have objections to its use (e.g. Jehovah's Witnesses).

2.2.2 Risk
- Theoretical risk of vCJD transmission.
- Circulatory overload.
- Hyperhydration
- Infusion reactions

2.2.3 Ordering
HAS is supplied by the transfusion laboratory.
HAS is available as 20% (100ml) or 4.5% (500ml) bottles.

2.2.4 Method of Administration:

HAS is administered by the intravenous route. The infusion rate should be adjusted according to individual circumstances and indications. The choice of concentration will depend on the patient's diagnosis.

2.2.5 Therapeutic indications

Aim of treatment The aim of treatment is to restore and maintain circulatory blood volume where volume deficiency has been demonstrated and use of colloid is appropriate. Albumin has a bigger effect on the intravascular volume and stays longer in the circulation and in some patients may be beneficial (Gastroenterology 1996 Oct; 111(4):1002-10). However the recent SAFE study did not show a difference in outcomes in patients who were hypovolaemic receiving albumin 4%. However various subgroup analysis did reveal interesting results: there was a trend towards decrease mortality in septic shock patients treated with albumin (relative risk of death, 0.87; 95%CI, 0.74-1.02). Increased mortality in trauma patients (relative risk,1.36; 95% CI, 0.99-1.86), especially those with traumatic injury (relative risk, 1.62; 95% CI, 1.12-2.34). was observed in the albumin treatment group.

Appropriate Specific indications

- Nephrotic Syndrome – in combination with diuretics.
- During drainage of ascitic fluid to prevent renal dysfunction due to increased renin activity and hyponatraemia (thereby preventing post-paracentesis circulatory dysfunction). The dose is as per Ascitic fluid drainage protocol – 100 ml of 20% HAS for every 3 litres of ascites drained)
- In severe burns after the first 24 hours (usage before this time has been demonstrated to cause paradoxical pulmonary oedema)
- In Acute Respiratory Distress Syndrome where use of diuretics has caused fall in effective plasma volume.
- In acute liver injury to support plasma oncotic pressure and bind excessive bilirubin, activated plasmin, toxins etc.
- In renal dialysis if the patient becomes hypotensive.
- In Hepatorenal Syndrome (HRS) along with Glypresin (a vasopressin analogue). The dose is as per HRS guideline – 1g/kg (Max 100g /day) per day for two or more days until improvement in renal function. Either 4.5% or 20% concentrations may be used depending on the fluid status of the patient.

Inappropriate indications

- Intravascular volume expansion after trauma or major surgery.
- As part of total parenteral nutrition.
- In long term supplementation of albumin in nephrotic syndrome.

The exact dose and strength of the HAS depends on the size of the patient, severity of illness and on continuing fluid / protein loss.

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Measures of adequacy of circulatory volume and not plasma albumin level should be used to determine the dose required.

2.2.6. Monitoring

The haemodynamic performance should be monitored regularly during the administration of HAS. This may include:

- Blood pressure and heart rate.
- Central venous pressure or pulmonary artery wedge pressure.
- Urine output
- Electrolytes, haemoglobin or haematocrit.

2.2.7 Contraindications

Hypersensitivity to albumin preparation or to any of its excipients.

2.2.8 Special warnings and precautions

HAS must be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk to patient. Examples of such conditions are:

- Decompensated cardiac failure
- Hypertension
- Oesophageal varices
- Pulmonary oedema
- Haemorrhagic diathesis
- Severe anaemia
- Renal and post renal anuria

Complications

- Allergic reaction / anaphylactic shock - the infusion should be stopped immediately and appropriate therapy implemented.
- Circulatory overload and hyper-hydration – the colloid osmotic pressure of 20% HAS is 4 times that of blood plasma hence care has to taken to ensure adequate hydration of the patient to prevent increased intracranial pressure especially in patients with acute liver failure.)
- Electrolyte imbalance – 20% HAS is relatively low in electrolytes compared to 4.5% HAS and is thus better suited for patients with renal impairment in conditions such as Hepatorenal failure / Renal dialysis / Nephrotic syndrome etc).
- Haemostasis - if a large volume of HAS have been used, it is advisable to request measurement of the patient's coagulation parameters and haematocrit in case they need correction.
- Hypervolaemia / Overdosing – adequate care and monitoring needs to be undertaken. The infusion should be stopped at the first signs or symptoms of cardiovascular overload (raised JVP, pulmonary oedema, hypertension, raised venous pressure, headache and dyspnoea).
  Mild reactions such as flush, urticaria, fever and nausea are rare and usually resolve on slowing the rate of infusion or stopping it completely.

Interaction with other medicinal products and other forms of interaction

- No specific interaction of HAS with other medicinal products is known.

Pregnancy and Lactation

- The safety of HAS in pregnancy has not been established in controlled clinical trials. However clinical experience suggests no harmful effects are to be expected on the course of the pregnancy, the foetus or neonate.

2.2.9 Pharmacological properties:

- Human albumin accounts quantitatively for more than half of the total protein in the plasma and represents about 10% of the protein synthesis activity of liver.
- The most important physiological function of albumin results from its contribution to oncotic pressure of blood and transport function (hormones, enzymes, medicinal products and toxins).
- Under normal circumstances, the average half-life of albumin is about 19 days. In critically ill patients, albumin can leak out of the vascular space in substantial amounts in an unpredictable rate.

2.2.10 Pharmaceutical information

- Please refer to product literature as this is product specific.

2.2.11 Instructions for use and handling and disposal:

- HAS solution is administered by the intravenous route.
- Albumin solution must not be diluted with water as this may cause haemolysis in recipients.
- If large volumes are administered, the product should be warmed to room temperature or body temperature before use.
- Do not use cloudy solutions or if they have deposits.
- Once the container has been opened, the contents should be used immediately. Any unused product must be discarded.

2.3 Endorsement

The guidelines will be approved by the Hospital Transfusion Committee
Final endorsement will be by the Clinical Governance Committee

2.4 Distribution

The guidelines will be recorded on SharePoint.
Staff will be made aware of the guidelines during induction and clinical update sessions, and via e Brief.

3. Implementation

3.1 The guidelines will be reviewed every three years or sooner if required in light of new evidence or statutory requirements.

3.2 The transfusion laboratory will maintain responsibility for storage and issue of HAS referring to laboratory SOP TRA-LP007. This SOP is reviewed 2 yearly.

3.3 If there are any adverse events related to the use of HAS, an incident form will be raised via DATIX, and the incident investigated by the transfusion operational management team and corrective and preventative actions implemented. If appropriate, a report will be made to SHOT and SABRE.

Glossary of Terms

HAS- Human Albumin Solution
SOP- Laboratory Standard Operational Procedure
DATIX- Electronic Adverse event and near miss reporting form
SHOT- Serious Hazards of Transfusion UK wide reporting system for adverse transfusion events and 'near misses'
SABRE- Serious Adverse Blood Reactions and Events This system allows reporters to electronically submit reports of serious adverse events or serious adverse reactions directly to the Medicines and Healthcare Products Regulatory Agency (MHRA)

References

European Medicines Agency Guidelines on the Core SPC for Human Albumin Solution, 2005

The SAFE study, NEJM 2004;350: 2247-2256

Human albumin administration in critically ill patients: systematic review of randomised controlled trials • Why albumin may not work BMJ Jul 1998**;** 317**:** 235 - 240

Cochrane Database Systematic Rev. 2006 Oct 18;(4)CD0051

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Appendix 1: Summary and Audit Trail

Development process								
Title:								
Human Albumin Solution (HAS) Infusion- Guideline for practice	Trustwide & Healthcare Economy		Trustwide		CBU		Dept	
	Multidisciplinary		Medical Staff	X	Allied Health Professionals		Nursing/ Midwifery	X

Reason for Development: (eg planned review of existing document, patient complaint, critical incident, publication of new evidence, inconsistent practice, NICE Guidance)

Inconsistent Practice

Development Lead:	Dr N Kumar- Consultant Gastroenterology		
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Development Team Members:
Dr K Rege- Consultant Haematology
Dr B Appadu- Consultant Anaesthetist
Martin Drury- Transfusion Laboratory Manager
Kaye Bowen -Transfusion Coordinator

Key sources of evidence used in the development of the document or the method of achieving consensus where evidence is not available:
European Medicines Agency Guidelines
The SAFE study
Cochrane Database Systematic Review

Consultation Process
Please list key Staff Members and Groups/Committees involved in the Consultation Process: Hospital Transfusion Team
Please identify committee(s) which will approve the policy (see flow chart for development) **:** Hospital Transfusion Committee Clinical Governance Committee

Once this form has been completed it should be sent to the Compliance Officer with the final copy of the policy