SEVEN HILLS TIMES

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LASSA FEVER

- Lassa fever is an acute viral hemorrhagic fever caused by "Lassa virus".
- Viral hemorrhagic fever is a clinical syndrome characterized by fever, bleeding tendency and shock.

EPIDEMIOLOGY

- Discovered in Nigeria, 1969.
- Endemic in parts of West Africa, Liberia, Nigeria, Sierra Leone and Guinea.
- Seasonal clustering – late rainy season and early dry season.
- Affects all age groups.
- Lassa virus also causes high foetal mortality and high mortality in pregnant women.

Recent outbreaks of lassa fever

First outbreak – 1969 (2 deaths)
March 2012 (623 suspected cases includes 70 deaths)
2013 (1195 cases with 39 deaths)
2014 (989 cases with 36 deaths)
16th January 2015 (6 cases)
25th February 2018 (1081 cases with 90 deaths)

ETIOLOGY

Caused by Lassa virus belongs to family Arenavirida. Rodents like Mastomys natelensis act as reservoir (virus lives in persistent asymptomatic state).

MODE OF TRANSMISSION

Rodent to Human

- inhalation of aerosalized virus and injestion of foos or materials contaminated
- catching and preparing Mastomys as a food

Human to Human

- direct contact with blood, secretions of infected humans
- needle stick or cut; inhalation of aerosolized virus.

PATHOGENESIS

Lassa fever
↓
Vascular damage
↓
Disorders of coagulation
↓
Immunological impairment
↓
Finally leads to end organ damage.

CLINICAL FEATURES

- A spectrum from asymptomatic (80%) to severe disease characterized by loss of plasma from small vessels (capillary leakage) and bleeding.
- Liver involvement is common, including jaundice.

Symptoms includes

Fever, Malaise, Fatigue, Body aches, Nausea, vomiting, diarrhea, headache, Facial edema, convulsions, mucosal bleeding(mouth, nose, eyes)

Internal bleeding, confusion, disorientation, coma, and death.

Clinical stages

STAGES	SYMPTOMS
Stage 1 (1- 3 days)	General weakness, malaise, high fever
Stage 2 (4 – 7days)	Sore throat, headache, back chest side or abdominal pain, conjunctivitis, nausea, vomiting, diarrhea, low BP, anemia.
Stage 3 (7- 14 days)	edema on face and neck, convulsions, mucosal bleeding, internal encephalopathy with confusion
Stage 4 (> 14 days)	Coma, death

DIAGNOSTIC TESTS

- Complete blood count – mild leucopenia and lymphopaenia / mild thrombocytopenia
- Urine analysis – proteinuria
- Serum – high BUN ratio
- High liver transaminases (AST>150U/L)
- Ig - M ELISA
- Lassa virus antigen
- RT – PCR
- Viral culture (7 – 10 days)

TREATMENT

- Supportive measures – monitor fluid, electrolyte and oxygen levels.
- Ribavirin – 60mg/Kg/day for 4 days iv

  ↓

  30mg /Kg/day orally.

  ADR:- mild hemolysis, suppression of erythropoesis

  CI:- contra indicated in pregnant women.
- Lassa virus vaccine.

PREVENTION

- Maintain clean environment.
- Good health seeking behavior.
- Proper hand washing and intake of nutritious food.
- Cover the food.
- Avoid contact with body fluids / secretions of the infected person.

Article

Zoledronic acid in the treatment of hypercalcemia of malignancy: results of the international clinical development program.

Hamilton Regional Cancer Centre, Hamilton, Ontario, Canada.

Abstract

This report summarizes results of the clinical development program evaluating zoledronic acid (Zometa; Novartis Pharmaceuticals Corp, East Hanover, NJ) in the treatment of hypercalcemia of malignancy (HCM). In addition to a phase I dose escalation trial, two randomized, double-blind, double-dummy studies were conducted in parallel to investigate the clinical efficacy and safety of 4 mg and 8 mg zoledronic acid in patients with moderate to severe HCM. Patients were treated with a single dose of zoledronic acid (4 or 8 mg) via 5-minute infusion or a control treatment, 90 mg pamidronate via 2-hour infusion. Patients who relapsed or had refractory HCM after initial treatment could be re-treated with 8 mg zoledronic acid. End points included rate of complete response, defined as normalization of corrected serum calcium by day 10, change in corrected serum calcium, time to relapse, duration of response, and bone biochemical markers.

Doses of > or =0.02 mg/kg were effective and nontoxic in the phase I study. In the controlled studies, 287 patients were randomized and evaluated for safety and 275 patients were evaluable for efficacy. The proportions of patients with a complete response by day 10 were 88.4% and 86.7% in the 4 mg and 8 mg zoledronic acid groups, respectively, compared with 69.7% in the 90 mg pamidronate group. Corrected serum calcium normalization occurred by day 4 in 45.3% of patients treated with 4 mg zoledronic acid, 55.6% of patients treated with 8 mg zoledronic acid, and 33.3% of patients treated with pamidronate. Mean change from baseline in corrected serum calcium also was greater with zoledronic acid than with pamidronate. Median times to relapse were significantly longer in both the zoledronic acid 4 mg and 8 mg groups compared with the pamidronate group. There were no significant differences in efficacy between the 4 mg and 8 mg zoledronic acid doses. Retreatment in 69 patients with relapsing or refractory hypercalcemia with 8 mg zoledronic acid resulted in a 52% complete response rate. Fever, hypophosphatemia, and asymptomatic hypocalcemia were the most common drug-related adverse events. These studies have shown that a short single intravenous dose of 4 mg or 8 mg zoledronic acid is effective in treating moderate to severe HCM. Zoledronic acid produced a higher rate of calcium normalization, faster onset of action, and longer time to relapse than pamidronate, while maintaining an excellent safety profile. The lower dose of 4 mg is recommended as initial therapy, with the 8 mg dose reserved for patients requiring retreatment.

Drug for newsletter

ZOLEDRONIC ACID: It is also known as Zoledronate .

Brand Name : Reclast, Zometa
Routes of Administration : Intravenous
Drug Class : Bisphosphonate
Molecular Weight : 272 g/mol
Molecular Formula : C5H10N2O7P2

PHARMACOKINETICS

Distribution : 56% plasma protein binding
Half Life : 146 hrs
Metabolism : It doesn't undergo biotransformation
Elimination : Renal excretion.

MECHANISM OF ACTION

Zoledronic acid is cytostatic and proapotic to a range of human cancer cell lines(breast,prostate,lung,myeloma). antiproliferative for human fetal osteoblast and promote their differentiation, potentially relevant for the treatment of bone metastasis in prostate cancer. zoledronic acid inhibits the proliferation of human endothelial cells invitro and is angiogenic. It also inhibits the tumor cell invasion through extra celluar matrix-antitumor activity.

Adverse Drug Reactions

- flu like syndrome consists of fever, chills, arthralgia, myalgias.
- Gastrointestinal reactions such as nausea and vomiting.
- Local reactions at the site of infusion such as oedema, flare
- Hypomagnesaemia, anemia, hypophosphatemia, hypokalemia,
- insomnia, anxiety, confusion, dysponia, cough.
- Urinary tract infection.

INDICATIONS: Multiple myeloma, osteoporosis, pagets disease

CONTRAINDICATIONS

Pregnancy, breast feeding, pediatrics, geriatrics, infants, neonates, diabetes mellitus, hypertension, cardiac arrthymias, seizures.

USES

- to treat hypercalcemia that may occur with cancer
- Zoledronic acid is also used with cancer chemotherapy to treat bone probems that may occur with multiple myeloma and other types of cancer(lung,breast)
- Osteoporosis
- Decreased bone mass following menopause

DRUG INTERACTION

- **DRUG-DRUG INTERACTION**

  Zoledronic acid + antibiotics (gentamycin), amphotericin-B, NSAIDS = harmful to kidneys.

- **DRUG-DISEASE INTERACTION**

  Zoledronic acid + osteonecrosis of the jaw (ONJ) = Zoledronic acid exacerbates the ONJ condition.
  Zoledronic acid + asthma=Increases bronchoconstriction.

- **DOSE**

  4mg/dose i.v infusion for hypercalcemia/oncology indications
  5mg/dose i.v infusion for Paget's disease/osteoporosis.

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A CLINICAL COMPARISON OF TOPICAL CIPROFLOXACIN VERSUS NEOMYCIN IN CHRONIC SUPPURATIVE OTITIS MEDIA (CSOM) PATIENTS PRESENTING TO SVIMS- SPMC(W) HOSPITAL, TIRUPATI

D .Roopa*, P. Sarvani

Objective

To compare the efficacy and safety of Topical Ciprofloxacin with Topical Neomycin in Chronic Suppurative Otitis Media (CSOM) patients.

Study design

A Retrospective observational study was conducted at ENT department of SVIMS- SPMC (W), Tirupati. Patients were enrolled based on inclusion and exclusion criteria.

Patients and Methods

CSOM patients who were treated with topical Ciprofloxacin or topical Neomycin with no loss of three weeks follow up are included in the study irrespective of their age and gender. CSOM patients undergone tympanoplasty and mastoidectomy (post operated CSOM patients) who were treated with Ciprofloxacin ear drops and Neomycin ear drops were also included in the study. The diagnostic parameters used were B/L X-ray Mastoids, Pure Tone Audiometry(PTA) and Impedance, other investigations include chest X-ray, coagulation profile, RBS, ECG. A total of 50 patients with diagnosis of Chronic Suppurative Otitis Media were selected for the study. Patients were categorized into 2 groups, Group A that was treated by topical Ciprofloxacin ear drops (n=25) and Group B that was treated by topical Neomycin ear drops (n=25). Outcomes were measured by disappearance of discharge and congestion at follow-up examination. SPSS 20 was used for data analysis, Chi-square test was used for analysis and P-value less than 0.05 were considered significant.

Results

Out of 50 subjects evaluated for the study 40% were male and remaining 60% were female. The age of patients varied from 15-67 years. The most prominent age group was found to be 31-40 years (figure 5.2). Table 5.2 presents the age distribution of CSOM patients. The laterity in our study subjects shows that right ear was affected in 40%, left ear in 44% while 16% of the patients had bilaterally affected ears, as shown in table 5.3 and the same is represented in fig 5.3 with a pie diagram. Topical Ciprofloxacin is more effective in earlier control of discharge and congestion in CSOM patients as compared to Neomycin (p-value was obtained as <0.05).

Conclusion

Ciprofloxacin otic drops are clinically more effective in the treatment of CSOM and can be used as an initial choice of topical antibiotic for CSOM patients.

Reference

1. Acuin J. Chronic suppurative otitis media: Burden of illness and management options. Geneve: World Health Organisation (WHO) 2006.
2. Kris M, Berktas M, Egeli, et al. The efficacy of topical ciprofloxacin in the treatment of chronic suppurative otitis medi. Ear nose throat J. 1998;20(77);904-5,909.

NETARSUDIL (RHOPRESSA 0.02%) FOR OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION

GEISHA MERIN VARGHESE*

RHOPRESSA 0.02% was evaluated in three randomized and controlled clinical trials, namely referred to as Study 301,302 and 304 in patients with open-angle glaucoma or ocular hypertension. Studies301 and 302 enrolled subjects with baseline IOP lower than 27 mmHg and Study 304 enrolled subjects with baseline IOP lower than 30 mmHg. The treatment duration was 3 months in Study 301, 12 months in Study 302, and 6 months in Study 304. The three studies demonstrated up to 5 mmHg reductions in IOP for subjects treated with RHOPRESSA 0.02% once daily in the evening.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening. If RHOPRESSA is to be used concomitantly with other topical ophthalmic drug products to lower IOP, administer each drug product at least 5 minutes apart.

INDICATIONS AND USAGE

RHOPRESSA (netarsudil ophthalmic solution) 0.02% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

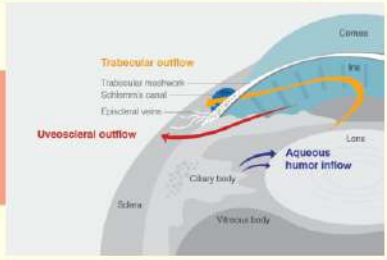

Figure 1: Mechanism of Netarsudil is increases outflow of aqueous humor

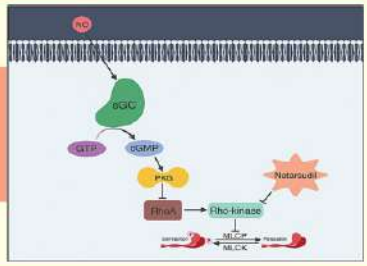

Figure 2: Netarsudil Rho kinase inhibitor.

MECHANISM OF ACTION

Netarsudil is a rho kinase inhibitor, which is believed to reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route. The exact mechanism is unknown.

ADVERSE REACTIONS

The most common ocular adverse reaction observed is conjunctival hyperemia and other common (approximately 20%) ocular adverse reactions reported were: corneal verticillata, instillation site pain, and conjunctival hemorrhage.

ADVERSE REACTIONS

Absorption: There were no quantifiable plasma concentrations of netarsudil post dose.

Metabolism: After topical ocular dosing, netarsudil is metabolized by esterases in the

DOSAGE FORMS AND STRENGTHS: Ophthalmic solution containing 0.2 mg/mL of netarsudil

STORAGE: Stored at 2 to 8 degree celcius until opened. After opening, kept at 2 to 25 degree celcius for upto 6 weeks.

CONCLUSION

Netarsudil is a new FDA approved drug. It has been shown to reduce IOP and there is no known systemic safety issues associated with the use.

REFERENCE

1. http://www.fda.gov/ Drugs/ Information on drugs / approved drugs /Reference ID: 4194833 http:/ /www.drugs .com/ search term = netarsudil

CURRENT BEST PRACTICE IN THE MANAGEMENT OF HYPERTENSIVE DISORDERS IN PREGNANCY

RADHIKA KRISHNAN*

Preeclampsia is a global health problem of increasing significance. It complicates 2%–8% of all pregnancies, contributes to 15% of preterm deliveries, and between 9% and 26% of maternal deaths worldwide.Hypertensive disorders of pregnancy can be sub classified into four groups – chronic hypertension, gestational hypertension, preeclampsia, and superimposed preeclampsia in the setting of chronic hypertension, as laid out in the ACOG (American Congress of Obstetricians and Gynecologists) guideline.

Table.1: The criteria set for severe preeclampsia in several national guidelines.

	National Institute for Clinical Excellence (2010)(any of the features below in combination with hypertension and proteinuria)	American College of Obstetricians and Gynecologists (2013)(any of the below with known preeclampsia)	American Society of Hypertension (2008)
Symptoms	Headach,Visual disturbance, Vomiting, Epigastric pain	Severe persistent right upper quadrant or epigastric pain, Cerebral or visual disturbance	Headache,Visual disturbance, Abdominal pain
Signs	Papilloedema, Clonus, Liver tenderness	Pulmonary edema	Oliguria,Early onset disease (<35 weeks) Nonreassuring fetal monitoring
Hypertension	Severe hypertension and proteinuria alone	Systolic BP>160mmHg DiastolicBP>110mmHg (on two occasions >4 h apart while on bed rest)	Diastolic >110mmHg
Other maternal disorders	HELLP syndrome Platelets<100×10^9/L AST or ALT >70	Platelets <100×10^9/L Liver enzymes >twice normal concentration Progressive renal insufficiency	Elevated creatinine , Nephrotic range proteinuria, Elevated AST or LDH

ANTENATAL CARE OF WOMEN WITH PREECLAMPSIA

Inpatient or Outpatient Management

- Ultrasound assessment of fetal well-being and Doppler studies of the umbilical artery performed.
- If blood pressure is persistently elevated (cutoff 150/100 mmHg), consideration should be given to the commencement of antihypertensive therapy.
- Women with stable blood pressure on treatment, normal laboratory studies, no concern about fetal well-being are candidates for outpatient management.

Choice of Antihypertensive in Moderate Hypertension

- NICE recommends that the first line antihypertensive should be Labetalol.
- Acceptable and commonly used alternatives are Methyldopa and Nifedipine.
- Nifedipine may be more effective in controlling blood pressure than labetalol or Hydralazine, but Labetalol was associated with fewer adverse perinatal events.

CONCLUSION

As preeclampsia complicates pregnancies, ACOG (American Congress of Obstetricians and Gynecologists) proposed specific antihypertensive to treat severe hypertension.

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- • World Health Organization. The World Health Report 2005: Make Every Mother and Child Count. Geneva, Switzerland: World Health Organization; 2005.
- Steegers EA, von Dadelszen P, Duvekot JJ, Pijnenborg R. Pre-eclampsia. Lancet. 2010; 376(9741): 631–644.

Perfect Clicks

10th Anniversary Celebrations with grateful presence of Dr.B Suresh, President of Pharmacy Council of India and Pr. K Chinnaswamy, President IACP, Chennai

Campus Placement Drive conducted by Divi's Laboratories, Chennai.

Fresher's Orientation Programme for the commencement of new academic year

Pharmacist Day Celebrations including Health awareness Rally and Door to door Health awareness Campaign in Rural area of Tirupati

A Two Days National conference on Current prospectives of Clinical Pharmacy and Pharmacotherapeutics was conducted in collaboration with SVIMS, Tirupati

Students Participated in Swachatha Seva in Primary Health Centre, Kammapalli.

Vanam-Manam Programme organised by College – Plantation in college Surroundings

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Study on the Clinical Pharmacist Intervention to Improve Health Related Quality of Life in Diabetic Patients in Rural Area

Dr. E Sunil Kumar*

Objective

The main objective of the study was to assess the impact of clinical pharmacist provided patient education on Quality of life outcomes in diabetic patients in rural population

Study design

A prospective observational parallel design study was conducted to outpatients of a Primary health Centre located in Tirupati rural area. Patients were enrolled and randomized in to control and intervention group based on inclusion and exclusion criteria.

Study Site

Primary Health Centre, Kammapalli, Situated in Tirupati Rural Area.

Procedure

The enrolled patients were segregated into control group (n=50) and intervention group (n=50). Patient counselling provided to intervention group in the aspects of disease awareness, usage of medication and life style modifications where the control group patients were not. The health related quality of life of patients measured for both groups were assessed for comparison.

Results

The mean blood glucose levels of intervention group were significantly decreased from 263±12mg/dl at baseline to 195.8±6.5 mg/dl at follow up, whereas control group shows no significant improvement in the management of diabetes (254 mg/dl to 248 mg/dl).

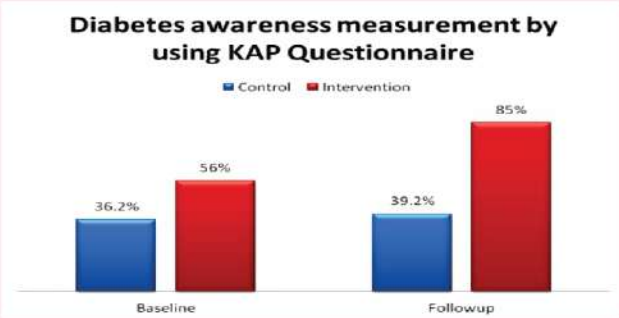

Fig.1: Diabetes awareness assessment

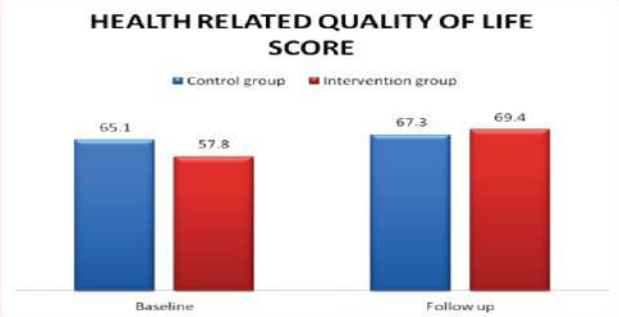

Fig.2: HRQOL assessment

In intervention group the percentage of correctly answered patients towards diabetes KAP questionnaire was significantly increased from 56±9.6% at baseline to 85±3.7% at follow up, whereas control group shows no significant improvement in the diabetes awareness (36.2% to 39.2%). The mean health related quality of life score is improved in the intervention group from 57.82±1.5 at baseline to 69.4±0.96 at follow up, where the control group shows a very little improvement in the health related quality of life(65.1 to 67.3).

Conclusion

The current study demonstrates that the clinical pharmacist provided patient counselling improved the health related quality of life (HRQOL) of diabetic patients in rural population by implementing the proper pharmaceutical care.

References

1. Ramanath KV, Santhosh Y L, Impact of clinical pharmacist provided patient education on qol outcome in type ii diabetes mellitus in rural population. Asian Journal of Pharmaceutical and Clinical Research 2011:4(3): 0974-2441.
2. Adepu R, Madhu S, Influence of post discharge counselling on health outcomes In diabetic and hypertensive patients, Asian Journal of Pharmaceutical and Clinical Research 2011:4(3): 0974-2441.

DRUG PROFILE

XOFLUZA(Baloxavir marboxil) for Influenza A and B Virus

M.D. Priyanka, Pharm D Intern

Approved Date : October 24, 2018
Brand Name : XOFLUZA
Generic Name : Baloxavir marboxil
Manufacturing Company: Gentech USA, Inc.
Dosage Form : Tablets
Molecular Formula : C27H23F2N3O7S
Molecular Weight : 571.552g/mol
Storage : 200Cto 250C temperature

IUPAC Name:
{(3R)-2-[(2S)-12,13-difluoro-9-thiatricyclo[9.4.0.0.{3,8}]pentadeca-1(15),3,5,7,11,13-hexane-241]-9,12-dioxo-5-oxa-1,2,8-triazatricyclo[8.4.0.0{3,8}]tetradeca-10,13-dien-11-41]oxy}methyl carbonate.

Dosage:

For ≥12 years and weight ≥40 kg:
40 to <80 kg: 40 mg PO as a single dose
≥80 kg: 80 mg PO as a single dose

Indications

For the treatment of influenza A and B virus infection in patients 12 and older who have been symptomatic for no more than 48 hours.

Mechanism of action of CAP endonuclease inhibitor

It is oral antiviral medicine that blocks an endonuclease enzyme within the flu virus which leads to stopping viral replication early in the 3 rd stage of influenza lifecycle.

Pharmacokinetics

Absorption : Tmax: 4h
Volume of distribution : 1180 (V/F, L)
Protein binding : 92.9 - 93.9 %
Route of elimination : 14.7 % of a single dose is excreted in the urine, and 80.1% excreted in the feces
Half life : Terminal elimination half-life: 79.1 h
Clearance : 10.3 L/h
Toxicity : Ld50 (oral, rats) : >2000 mg/kg

Adverse Drug Reaction : Diarrhea(3.0%), Bronchitis(2.6%) ; Nausea(1.3%), Sinusitis (1.1%)

Drug Interaction

The therapeutic efficacy of varicella zoster vaccine can be decreased when used in combination with baloxavir marboxil.

Contraindications

in patients with a history of hypersensitivity to baloxavir .marboxil (or) any of its ingredients.

A BRIEF REVIEW ON HIV VACCINE

N.Lakshmi Likitha Reddy, Pharm D Intern

Human Immunodeficiency Virus (HIV) is responsible for millions of deaths around the world and in the absence of available treatment capable of a cure, only the vaccine can offer prevention against this virus.

HIV-1 integrates its genetic material in the host's DNA, an event currently impossible to revert1. A small number of people who are infected with HIV-1 produce very special antibodies. These antibodies do not just fight one virus strain, but neutralize almost all known virus strains. Research into developing an HIV vaccine focuses on discovering the factors responsible for the production of such antibodies. HIV-1 genome influences immune reaction2. Therefore, the design of a vaccine against HIV-1 is paramount in order to prepare the immune system to act promptly and neutralize this pathogen before the establishment of a permanent infection.

Although several vaccine regimens and trials have been tested for HIV/AIDS at pre-clinical level, only one vaccine trial, i.e., RV144 showed only modest ~30% protection in human clinical trials.

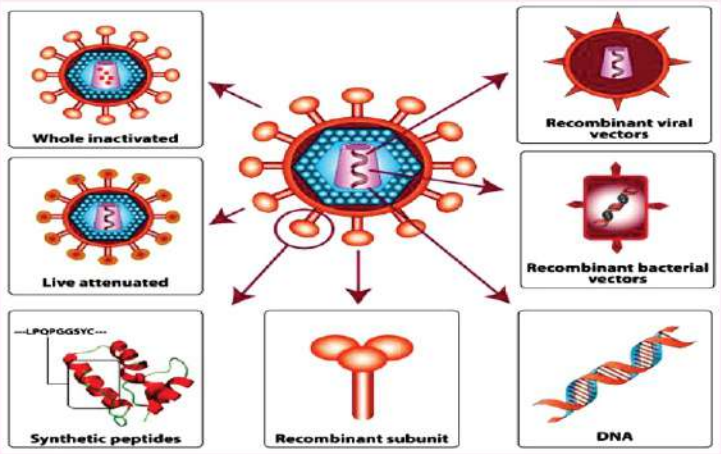

Fig.3: Various approaches for the development of HIV vaccine

Although, the possibility of achieving a successful HIV vaccine lies elusive, recent breakthroughs had been very promising3. In 2009, the phase III clinical trial RV144 vaccine (ClinicalTrials.gov number, NCT00223080) in Thailand was the first to demonstrate modest protection against HIV-1 infection, with an estimated vaccine efficacy of 31.2% after the three and a half year trial4. HIV inactivation deserves a more vigorous exploration in HIV vaccine research.

Trial	Vaccine	Location	Result
VAX004	Antibody vaccine	US, Europe	No Efficacy
VAX003	Antibody vaccine	Thailand	No Efficacy
HVTN502	T Cell vaccine	US	No Efficacy, Increased infection in recipients
HVTN502	T Cell vaccine	South Africa	No Efficacy, Increased infection in male recipients
RV114	Antibody and T cell vaccines	Thailand	Estimated 31.2% vaccine efficacy at 42 mo; 60% efficacy at 12mo;
HVTN505	Antibody and T cell vaccines	US	No Efficacy

Table.1: Selected HIV Vaccine Efficiency trials

REFERENCES

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2. Roger D. Kouyos, Peter Rusert, Claus Kadelka, Michael Huber, Alex Marzel, et.al. Tracing HIV-1 strains that imprint broadly neutralizing antibody responses. Nature, 2018.
3. Venkateswarlu. Current Scenario and Future Prospects of HIV Vaccines Chamcha University of Louisiana, USA Chamcha, J AIDS Clin Res 2016, 7:11.
4. Daniela Damjanovic, LiweiHe, et.al., In vitro assessment of biological activity and stability of the ALVAC-HIV vaccine. Vaccine. 2018, 36 (37): 5636-5644.

Perfect Clicks

A glimpse of Fresher's Day Celebrations Month and Year

Students attended the Pharmacy Practice Module in JSS University, Mysuru.

Vigilance awareness week, in collaboration with Anti Corruption Bureau

Swine Flu Awareness Rally conducted by College in Tirupati

Awareness Rally on AIDS in Rural Areas of Tirupati

Guest lecture on topic "Know Your Profession"

Free Medical Training programme in Anganwadi centres of Ramachandrapuram Mandal

Kishori Vikasam Phase II campaign with the theme of Beti Bachao- Beti Padao